IN THE UNITED STATES DISTRICT COURT FOR THE

SOUTHERN DISTRICT OF WEST VIRGINIA, HUNTINGTON DIVISION

BEFORE THE HONORABLE ROBERT C. CHAMBERS, JUDGE

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CLAUDE R. KNIGHT and CLAUDIA STEVENS, individually and as personal representatives of the Estate of BETTY ERLENE KNIGHT, deceased,

Plaintiffs,

vs. No. 3:15-CV-06424

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., Volume 9
Pages 1776 through 1969

Defendant.
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REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL

WEDNESDAY, OCTOBER 17, 2018, 9:00 A.M.

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INDEX

HUNTINGTON, WEST VIRGINIA

WEDNESDAY, OCTOBER 17, 2018, 9:04 A.M.

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(Jury not present.)

THE COURT: Good morning.

MR. CHILDERS: Good morning, Your Honor.

MR. LEWIS: Good morning, Your Honor.

THE COURT: So I understand there's a matter we need to take up before we come back for closings?

MR. LEWIS: Yes, Your Honor. Thank you.

The issue relates to economic damages, in other words, medical bills and funeral expenses, things of that sort.

THE COURT: Right.

MR. LEWIS: There was no testimony where the claimed medical bills or other expenses were identified. There is the stipulation that medical bills generally are -- we've stipulated they are reasonable and necessary, no burden to show that they weren't caused, but there has to be some testimony in the record of the identification of what those claimed expenses are. And we went through the transcript, and we didn't see that from any of the plaintiffs or anybody.

THE COURT: Okay. What was the stipulation exactly?

MR. CHILDERS: The stipulation is that the medical

bills, once redacted, are admissible.

So if you recall, Your Honor, I moved them into evidence before the plaintiffs testified. And if we didn't have that stipulation, I would have had them go through the medical bills and talk about them. But the stipulation is clear, it doesn't -- it says they're admissible, and that BI has the opportunity, if they choose, to put up evidence that says they don't believe they're related. That evidence never came in.

MR. LEWIS: Well, the stipulation says that the medical bills were reasonable and necessary by stipulation. That means there's no expert testimony required to connect those. That doesn't mean that they don't have to identify what they're claiming, including other expenses.

And --

THE COURT: Isn't that included in the documentation? Isn't there documentation about the expenses?

MR. CHILDERS: Yes, sir. It's actual bills. And then we have the records that match up to when the bills were incurred.

MR. LEWIS: But, again, there was no testimony that these are the identified claimed expenses. That's what is troubling me. The jury hasn't heard one sentence about any of that.

THE COURT: If the bills have been the object of the stipulation that finds them -- that declares that they're reasonable and necessary, and that stipulation is entered as a matter of the record, I don't see what else they would need. They don't need a witness to testify that the bills were incurred. By being admitted into evidence, it seems to me they're agreed by the parties to be the bills that were incurred.

MR. LEWIS: I disagree, Your Honor. So, please, I think for the record, note our objection that we have an objection to the plaintiffs being able to claim economic expenses because we don't think they've established the proper foundation, and I'll let the Court rule on that.

THE COURT: Okay. I haven't seen the stipulation.

MR. CHILDERS: May I read it into the record, Your Honor?

THE COURT: Yes, please.

MR. CHILDERS: Sorry. I didn't realize this was an issue this morning.

This is stipulation No. 2: The parties stipulate that the medical bills incurred by Betty Knight --

THE COURT: Hold on. Let's let the jurors pass.

MR. CHILDERS: Sorry. Yes, sir.

THE COURT: Good morning.

(Brief pause in proceedings.)

MR. CHILDERS: Sorry about that, Your Honor.

THE COURT: Go ahead.

MR. CHILDERS: I'll start over, if I can.

Stipulation No. 2: The parties stipulate that the medical bills incurred by Betty Knight were reasonable and necessary for her care and treatment, and that each is admissible, once redacted to remove personal identification information and collateral source information; that defendant reserves the right to contest whether any particular medical bill is relevant and/or was related to Ms. Knight's gastrointestinal bleed or the sequelae thereof.

And, Your Honor, we redacted them, we took out the personal information, and then we admitted them into evidence.

MR. LEWIS: And let me just respond by saying the reasonable and necessary obviates the need for expert testimony. The admissibility -- there is no question that we did not object to the admissibility. But in order for the jury to find economic damages, they still have to have some testimony that these were the bills incurred. That's our view.

THE COURT: That stipulation says the bills were incurred.

MR. CHILDERS: That's exactly right. It's the first sentence.

THE COURT: All right. I think that is sufficient. I deny your objection to it.

MR. LEWIS: Thank you.

THE COURT: While I've got you here, I've got another proceeding I'm going to take up after we conclude, but after I got my copy of the instructions last night, I realized that some things needed to be moved around, and so Blake is doing that. I can tell you very quickly what they are, and I think this will cover it.

I moved the discussion of a learned treatise and put it right after expert witness. So the expert is explained and then the learned treatise.

I took the greater weight of the evidence section, the burden of proof, I put that at the beginning of the statement of plaintiffs' claims. And I added a sentence something to the effect that the plaintiff must establish each element of their claims by a greater weight of the evidence, and then that is defined. And then I go to the paragraph which says here are the five causes of action and those things.

And then there was instructions on punitive damages, and the punitive issue I moved after the fraud elements and before the other general damage instructions. So it will read -- the order will be that we've got a paragraph saying here are the four or five causes of action. Then here are

the elements of each. And after fraud, then I have the law on punitive damages, and then after that the general damage instruction.

MR. CHILDERS: Your Honor, there was one more section. I think we've e-mailed it to Blake and the defendants.

In the damages section, the way it's written out starts with wrongful death and then personal injury, and my understanding is the jury would have to find personal injury first before they would even get to the wrongful death. So it's a little -- the way it is written out, it almost sounds like you have to find wrongful death before you can award any damages. And so all we would ask is you just switch those in order.

THE COURT: What do you think?

MR. LEWIS: Did the Court just follow a pattern -- I'm not sure that's the law, but --

THE COURT: I don't think it's a matter of the law. I think what you're saying, and I think I probably agree, is that if the jury finds that you've violated your conduct duties, then in order to award any damages, they have to find that there was injury proximately caused by your conduct. And there has to be personal injury to her before there is wrongful death of her, because that is what the evidence says. If there was proximate cause, it's first

that she was injured by having the bleed, et cetera, and then the death.

MR. LEWIS: I don't think it's a big deal, so no objection to that switch.

THE COURT: All right. I think that probably at least makes it less likely they're going to be confused if they start sifting through this stuff, so I'll make that change, too.

MR. CHILDERS: Thank you, Your Honor.

MR. LEWIS: And just for the record, no objection to the movement of the instructions that the Court just identified.

THE COURT: All right.

MR. CHILDERS: Thank you, Judge.

THE COURT: Anything else?

If not, you're excused at this point. My next proceeding will take 15 or 20 minutes, and then we'll start.

MR. CHILDERS: Thank you, Your Honor.

MR. MOSKOW: Thank you, Your Honor.

(Recess taken at 9:15 a.m.)

(9:50 a.m. in open court)

THE COURT: We have one matter to take up that I didn't realize.

MS. JONES: I think so, Your Honor.

MR. LEWIS: I guess there's some objections to our slides.

THE COURT: Well, that's another matter then.

All right. Are you folks ready?

MS. JONES: We're ready.

THE COURT: So I didn't realize until I got finished a few minutes ago that through the course of emails last night defendant proposed some additional language and plaintiff responded. And then defendant responded to that.

And, so, I wanted to take that up and first make sure that the Court understands and rules on anything if it's still a matter at issue and then, secondly, to make sure that the parties protected the record. So --

MR. CHILDERS: My understanding was that that charge has been withdrawn.

THE COURT: Well, so first I think that's -- I understood that you all were proposing additional language. Once proposed, plaintiff responded with a proposed addition. And then in response to that, you said you'd rather not have the original instruction. So --

MR. LEWIS: May I clarify?

THE COURT: Yes, sure.

MR. LEWIS: We proposed an instruction consistent with our discussion yesterday on punitive damages related to -- and I was trying to look at that language but --

THE COURT: As I recall, the language was something to the effect that in determining whether to find punitive damages, the jury could consider, should consider, may consider the warnings which the defendant attempted to give or something to that effect.

MR. LEWIS: Right out of the case law as we discussed.

Our view, Your Honor, is to either give our instruction as we crafted it or no instruction at all, but we're not withdrawing it. We just think that the plaintiffs' addition doesn't have any basis in the law. It's just a superfluous add to twist the law in their favor there.

THE COURT: Well, okay.

MR. MOSKOW: If I may, Your Honor, the, the addition of any language to the pattern instruction isn't changed. Our position is that if the jury's to properly consider the evidence, it should be balanced. They should consider whether there was an effort or there was not. That's it.

MR. LEWIS: But the case, the case actually finds that if we made an attempt to warn, there's no finding of

actual malice. We dialed that back to -- at the Court's suggestion to say they may consider that fact for purposes of considering whether we acted with actual malice. I don't think there's any necessity to put the language proposed by the plaintiffs because that's, they're already arguing that.

MR. CHILDERS: I'm confused. They sent an email saying they didn't want it anymore.

THE COURT: Well, I think what the email said was they didn't want it if your language was going to be included in it.

MR. CHILDERS: Understood.

THE COURT: You know, I'm going to give the instruction as the defendant tendered it. I do think it is fair to say.

Clearly the evidence here is that the defendant made an effort to include warnings. Plaintiffs themselves have cited the fact that this label was modified over the course of time to add additional statements that could be interpreted as warnings.

I think -- so I think the evidence is clear there was an attempt to warn. And I do not think it's improper to -- since that is the very conduct that might and should be an issue in the jury's determination as to all of the elements of the claim, including the punitive claim, I think it's fair to say that.

So I'm going to add that sentence as tendered by the defendant. Of course, in argument plaintiffs are certainly free to argue that the efforts were woefully inadequate or however they want to argue it based on the evidence. But I think that is a matter for argument and not a defect in the proposed instruction.

MR. MOSKOW: Thank you, Your Honor. Just for the record, we'll note our objection to an alteration of the pattern instruction.

THE COURT: All right. We'll add that language. And I think Blake just passed out copies of the final instructions. You know, I want to give you a minute to see if you're satisfied with the order in which things are now and so forth. We need to do this quickly.

MR. MOSKOW: The plaintiff just is trying to identify whether or not some language got left out when it was redone. We're dealing with that now.

THE COURT: Okay.

(Pause)

THE COURT: All right. It will take him just a couple minutes. But in what we gave you I didn't realize in the damage section we inadvertently split the wrongful death language into two parts. We're moving that.

MR. MOSKOW: Thank you, Your Honor.

THE COURT: Yeah. He's going to fix that and then

he's going to add the sentence that I granted over plaintiffs' objection.

MR. LEWIS: We received notice of some objections to our opening -- or to our closing slides.

THE COURT: Okay.

MR. LEWIS: I don't know if the Court wants to take that up while this is being worked on.

THE COURT: I do.

MR. CHILDERS: Your Honor, we have objections to several slides, but they're basically all the same thing.

There are multiple places in their presentation where they are quoting language from the trial transcripts and saying on the bottom of the slide where it came from the trial transcript.

Our understanding was that was not something we were supposed to do, that that would indicate to the jury that there are transcripts that they may be able to see.

All we're asking is take out the quotation marks. Take out the references to trial transcripts so they don't get an idea that they can come in here and ask to see those transcripts. We're not asking the language be changed.

MR. LEWIS: Well, I guess we can take out the reference, but putting quotation -- it's not an actual clip from the transcript. It's just quotation marks around testimony. We could do that whether there's a trial

transcript or not. The trial transcripts are the official record.

THE COURT: All right. Why don't you just take out the, --

MR. LEWIS: The citations?

THE COURT: -- the citations to the transcript record. Can you do that?

MR. LEWIS: Let me make sure we can do that. Okay.

MR. CHILDERS: And then we had one other objection. Their very first slide they have a quote from me in opening statement which is clearly not evidence. So my understanding is we're here to argue evidence. And if they're going to start with arguing statements of counsel, that's inappropriate.

MR. LEWIS: Well, what we have at the last -- first of all, that's done all the time.

THE COURT: Yeah. I mean, I'm going to let -- they can certainly tell the jury what they believe you said in the outline of your case and then challenge whether or not you've established that or proven that or whatever. So --

MR. CHILDERS: Thank you, Your Honor.

MR. LEWIS: Thank you, Your Honor.

THE COURT: Blake's emailing to each of you this

last version while he's also printing it off for me. So I would like you to look at that. We'll take a couple minutes to print it off maybe before we bring the jury in.

(Pause)

THE COURT: Also have you all looked at the verdict form? Are we okay there?

MR. CHILDERS: Plaintiffs are fine with it, Your Honor.

MR. MOSKOW: We provided it last night and I haven't seen any objection.

MS. JONES: Subject to our objections raised yesterday, I think it's consistent with what we discussed with the Court.

THE COURT: All right.

(Pause)

THE COURT: While we're doing this, let me also just mention something so you're not taken by surprise.

I'll read the instructions. But when I get to what is essentially the last very brief section of my final instructions, and I think it probably says "closing instruction" or something at the end, at that point, I'll stop. We'll do closing statements.

And then after closing statements I'm going to read that last brief portion, the instruction which is simply instructions for the jury about selecting a foreperson,

return of a verdict, and so forth.

And I understand the parties agree an hour and 15 minutes. Are you going to split it or anything or is this one lawyer for all of them?

MR. CHILDERS: One for us, Your Honor.

MS. JONES: Same, Your Honor.

THE COURT: All right. Also a minor matter while we're waiting.

Terry advises me that with respect to the exhibit lists that you all have which we plan to give to the jury along with the admitted exhibits, there's the cover sheet. Each of you have a different cover sheet, plaintiffs' exhibit list, defendant's first amended exhibit list. I assume each side is okay with those going back.

MR. MOSKOW: On behalf of plaintiff, Your Honor, yes, we're fine with that.

THE COURT: Do you know what I'm talking about? Want to look at them real quick?

MR. LEWIS: May I approach, Your Honor?

THE COURT: Yes.

MR. MOSKOW: Your Honor, subject to all of the Court's rulings, the plaintiffs accept the final jury instructions.

THE COURT: All right.

MR. LEWIS: Do we need a cover sheet?

THE COURT: Well, you kind of do in the first exhibit maybe. I just -- we don't need it really with the plaintiffs. Terry can handwrite that in.

THE CLERK: I can probably cursor down and fix it.

MR. LEWIS: I mean, it's just a lot of confusing verbiage. I feel like little things like that can really confuse folks.

THE COURT: I don't disagree and it shouldn't matter to the jury whose exhibit it is.

MR. LEWIS: If we just have a list.

THE COURT: But if we don't have that cover sheet, is your first exhibit --

THE CLERK: I can cursor down. I can put a header that just says --

THE COURT: Don't even do that.

MR. LEWIS: They just need a number.

THE COURT: Yeah. All right. So I'm going to remove these cover sheets and they'll be provided literally just a list of exhibits by number, no header identifying which party submitted it or any of the other language.

MR. MOSKOW: That's fine, Your Honor. Thank you.

THE COURT: All right. Are we ready to proceed?

MR. CHILDERS: Yes, Your Honor.

MS. JONES: Yes, Your Honor.

THE COURT: Let's bring the jury in.

(Jury returned into the courtroom at 10:10 a.m.)

THE COURT: All right. You may be seated.

Good morning, ladies and gentlemen. Sorry for the delay. I had a criminal matter I had to take up which took a little bit longer than I thought. And then I had a few minor things to work out with the lawyers before we could really start, but we're ready to go now.

So now I want to give you final instructions. I will now explain the law in this case and how to apply it in your deliberations. You must reach your verdict based only on the evidence presented in this courtroom and the law as I give it to you in these instructions and any instructions during the trial.

You must follow the law as I explain it to you, even if you do not agree with the law. You must consider all of the evidence, no matter which party produced the evidence. You must base your verdict solely upon the evidence presented.

The evidence is all the testimony received from the witnesses, including the depositions, the exhibits introduced into evidence, documents that were admitted as part of the evidence, and the facts that the parties agreed are true.

Evidence can sometimes, may be direct or indirect. You may hear the term "circumstantial evidence."

Direct evidence means a fact was proven by a document

or by testimony from a witness who saw or heard the fact first-hand. An example of direct evidence is testimony from a witness who testified, "I was outside and it was raining." The witness saw it raining. This is direct evidence that it was raining.

When direct evidence is proven, you may infer other facts that naturally or logically follow according to your common experience. This is called indirect or circumstantial evidence.

An example of indirect evidence is testimony from a witness who did not see it raining but saw someone come inside wearing a raincoat covered with drops of water. The witness did not personally see it raining, but inferred that it was raining because of seeing the raincoat covered with water. This is indirect evidence of the fact that it is raining.

So you may draw reasonable inferences from the evidence but there must be a logical connection between the proven facts and your conclusion.

You may use your experience and common sense in reaching conclusions from facts that have been proven. From a legal standpoint, it makes no difference whether the evidence is direct or indirect or circumstantial.

You may choose to believe or disbelieve either kind. You should give every type of evidence whatever weight you

believe that particular evidence deserves. You are the judges of the evidence. You can believe or not believe any part of a witness's testimony.

In evaluating the believability of a witness's testimony, you may consider:

First, how did the witness appear and act while testifying?

Second, did the witness have the opportunity to see, hear, or know the things about which he or she has testified?

Next, was the witness's memory accurate or unclear?

Then does the witness have any bias or interest in the case's outcome?

And, last, was the testimony reasonable or unreasonable?

You may use any or all of these reasons to weigh a witness's testimony in your deliberations.

Now, you've heard testimony from several expert witnesses. An expert witness is a witness who has more specialized knowledge than an average person has about a particular subject.

This specialized knowledge may be from education, training, or experience. In deciding the weight to give an expert's testimony, you may consider the witness's skill, knowledge, experience, background, and familiarity with the

facts in this case.

You may also consider the expert's truthfulness and take into account whether the expert's testimony is sensible or reliable and compare it to the other evidence.

After considering the facts and circumstances on which an expert's opinion is based, you may give each expert's -- each expert's testimony the weight you believe it is entitled to receive. You can believe or not believe any part of an expert's testimony.

Now, the parties have used what we call learned treatises. That's where they've had medical literature and used parts of it.

Passages or statements contained in published treatises, periodicals, or journals have been testified to by experts or have been used by counsel in the examination of expert witnesses.

You may consider the passages or statements testified to or used from these published treatises, periodicals, or journals along with all the other evidence material to the issues in this case.

The rules of evidence allow these passages or statements to be testified to, read into evidence, and considered by the jury, but do not permit the publications themselves to be submitted to the jury as exhibits for review in the jury room.

Also during this trial depositions of several witnesses were presented and received into evidence. A deposition is testimony given by a witness under oath before trial.

The lawyers question the witness who swears to tell the truth and the questions and answers are recorded. You should use the same methods in evaluating the deposition testimony that you use for a witness testifying in court. You are the judges of the witness's testimony whether it is in court or in a deposition.

Further, some of the witnesses played by video testified in German and had their testimony translated into English. The fact that a witness testified in a foreign language should not be considered in your evaluation of that witness's testimony.

You should consider and decide this case as a dispute between persons of equal standing in the community, of equal worth, and holding the same or similar stations in life. A corporation is entitled to the same fair trial as a private individual. All persons, including corporations and other organizations, stand equal before the law and are to be treated as equals.

Now, some evidence or circumstances in this case may make you sympathetic to one of the parties. Sympathy, of course, is a natural human emotion. However, the law and your oath as jurors require that you disregard sympathy and

not allow it to influence your verdict. Your verdict must be based only on the law and the evidence.

Now, plaintiffs must prove each element of each of their claims by a greater weight of the evidence. Sometimes lawyers refer to that as the preponderance of the evidence. It simply means greater weight.

The greater weight of the evidence means evidence that you believe outweighs the evidence opposed to it. It means that the evidence is more persuasive or convincing.

If the plaintiffs prove their claims by a greater -- by the greater weight of the evidence, then you may find in favor of them. If the plaintiffs did not prove their claims by a greater weight of the evidence, then you may find for BI.

If you believe that the evidence is equally balanced, the plaintiffs have not established their claims by a greater weight of the evidence, then you may find for the defendants.

Now, here the plaintiffs claim that Pradaxa was a proximate cause of Ms. Knight's injuries, including her death. Plaintiffs' case is based on five separate claims against the defendant. These claims are:

First, that the warnings provided with Pradaxa were inadequate;

Second, that the defendant failed to exercise

reasonable care in formulating the warnings for Pradaxa;

Next, that the defendant breached an express warranty covering Pradaxa;

Then that BI breached an implied warranty covering Pradaxa;

And that BI committed fraud by misrepresenting facts related to Pradaxa.

Of course the defendant, BI, denies any failure to warn, negligence, breach of any warranty, or fraud claim and denies that any wrongful conduct by it caused any injuries to Ms. Knight or caused or contributed to her death.

The defendant BI further asserts that Ms. Knight's death was due to other causes.

Now, I will instruct you and explain the law regarding each of these claims separately. You will consider them and decide each claim separately.

First, the proximate cause of an injury is a cause that produces the injury in the natural and probable sequence of events and without which the injury would not have occurred.

You're to decide whether Boehringer's conduct was negligent and whether it proximately caused Betty Knight's harm.

The defendant's conduct proximately caused the injury if the conduct, in the natural and probable sequence of events, brought about the injury, and the injury; second,

the injury would not have happened without the conduct.

Of course, there can be more than one proximate cause of an injury. As such, plaintiffs are not required to prove that the defendant's negligence was the sole proximate cause or only cause of Betty Knight's injuries, including her death.

Now, the only way that plaintiffs can prove some of the elements of their claims is through expert testimony that is grounded in reasonable medical or scientific certainty. By this I mean that if you do not accept the expert testimony presented by plaintiff about a factual issue that must be proved through expert testimony, then you should not find in favor of the plaintiff on that issue.

For example, the only way plaintiffs can prove that Pradaxa's warnings were inadequate is through expert testimony. In addition, the only way plaintiffs can prove that Pradaxa was responsible for Ms. Knight's injuries or death is through expert testimony.

You heard all of the evidence regarding Pradaxa's label approved by regulatory agencies outside of the United States. Because the standards governing labeling vary by country, the fact that the Pradaxa label available outside the United States differs from the FDA approved label in some respects does not establish that the Pradaxa label available in the United States is inadequate. But you may

consider the labeling for Pradaxa outside the United States only to the extent that it provides evidence of the defendant's knowledge regarding Pradaxa.

You heard testimony regarding the clinical testing of the 75-milligram dose of Pradaxa. Plaintiffs are not making a claim, and BI cannot be held liable, for failure to perform clinical testing on Pradaxa.

When deciding whether BI failed to warn, you must consider only the information that BI provided or failed to provide about the risks and dangers associated with the use of Pradaxa.

BI has a duty to provide adequate warnings to Mrs. Knight. Because Pradaxa is a prescription medicine available only with the approval of a healthcare professional, when considering the adequacy of the warnings provided you may consider the information that BI provided to Ms. Knight's doctors through the physician label.

BI is not permitted to change the patient Medication Guide without prior approval, FDA approval. And plaintiffs cannot bring a claim based on any defect in the patient Medication Guide.

Thus, when considering if the warnings provided by BI were adequate, you cannot consider any defect in the patient Medication Guide as the basis for your verdict.

But because BI can change the physician's label without

prior FDA approval, you may consider if the physician's label fails to probably warn.

In the course of this trial evidence has been introduced that Pradaxa sold by BI complied with certain federal or state laws or administrative regulations.

When you are determining the issue of failure to warn, negligence, and breach of warranty, you may consider BI's compliance with any federal or state law or administrative regulation that prescribed standards for the manufacture of Pradaxa existing at the time that Pradaxa was manufactured.

Compliance with appropriate regulations is competent evidence that BI exercised due care in marketing Pradaxa. Failure to comply with an appropriate regulation is competent evidence that BI did not exercise due care in marketing Pradaxa.

Plaintiffs claim that Ms. Knight was injured by a defect in Pradaxa which was sold by BI. To recover plaintiffs must prove by a greater weight of the evidence all of the following:

First, that BI sold the Pradaxa taken by Ms. Knight;

Second, that the Pradaxa was defective when it left possession of BI;

And, third, the defect in Pradaxa was a proximate cause of Ms. Knight's injury, including her death.

A product is defective if it is not reasonably safe for

its intended use. A product defect may be established by evidence proving the warnings, instructions, or labels accompanying the product were inadequate to warn of the dangers associated with the product.

Plaintiffs claim that Pradaxa's warnings of potential risks were inadequate. This is referred to as strict liability failure to warn.

In considering this claim, you are instructed that not all dangers require warnings. You must decide what a reasonably prudent manufacturer would have warned in regard to the safety of Pradaxa at the time of its manufacture.

To establish this claim, plaintiffs must prove all of the following elements:

First, that BI manufactured Pradaxa;

And, second, that use -- that a use of Pradaxa which was reasonably foreseeable to the manufacturer involved a substantial danger that would not be readily recognized by the ordinary user of Pradaxa;

And, third, that BI failed to give adequate warnings of such danger;

And, fourth, that the manufacturer's failure to provide adequate warning was a proximate cause of Ms. Knight's injuries, including death.

Now, Boehringer as the manufacturer of prescription drugs has a duty to warn patients directly about the risks

of Pradaxa. It is Boehringer's duty, and not the responsibility of the FDA or anyone else, to provide warnings, instructions, and directions for the use of Pradaxa.

Therefore, BI is required by law to provide adequate warnings for Pradaxa and to ensure that the warnings, directions, and instructions regarding Pradaxa's use remain adequate as long as Pradaxa is on the market.

Now, in addition to plaintiffs' claim that Pradaxa was defective by virtue of inadequate warnings, plaintiffs also claim that BI was negligent by not using reasonable care to warn about Pradaxa's dangerous condition or about the facts that make Pradaxa likely to be dangerous.

To establish this claim, the plaintiffs must prove by a greater weight of the evidence all of these following matters:

First, that BI sold Pradaxa;

Second, that BI knew or reasonably should have known that Pradaxa was dangerous or was likely to be dangerous if used in a reasonably foreseeable manner;

And, third, BI knew or reasonably should have known that users would not realize the danger;

And, fourth, BI failed to warn adequately of the danger;

And, fifth, that a reasonable seller under the same or

similar circumstances would have warned of the danger;

And, sixth, that Ms. Knight was injured;

And, last, that BI's failure to warn was a proximate cause of Ms. Knight's injuries, including death.

Now, the defendant as a manufacturer of prescription drugs has a duty to warn patients directly about the risks of Pradaxa. It is the defendant's duty, not the responsibility of the FDA or anyone else, to provide warnings, instructions, and directions for the use of Pradaxa.

Therefore, BI is required by law to provide adequate warnings for Pradaxa and to ensure that the warnings, directions, and instructions regarding Pradaxa's use remain adequate as long as Pradaxa is on the market.

Negligence is the failure to use reasonable care.

A seller is negligent if it fails to use the amount of care in warning about the product that is -- that a reasonably careful seller would use in similar circumstances to avoid exposing others to a foreseeable risk of harm.

In determining whether BI used reasonable care, you should balance what BI knew or should have known about the likelihood and seriousness of potential harm from Pradaxa against the burden of taking safety measures to reduce or avoid that harm.

BI may be liable for failure to warn only if plaintiffs

prove that a failure to provide adequate warnings was the legal cause of Ms. Knight's injury or death.

First, plaintiffs must establish that Pradaxa caused Ms. Knight's injury, including death;

Second, plaintiffs must prove that a different warning would have been -- made a difference. In other words, plaintiff must prove that the warning suggested by them would have caused Ms. Knight to act differently or otherwise change her behavior in a manner that would have avoided her injuries, including death.

If plaintiffs did not prove it is more likely than not that Ms. Knight read the warnings provided by BI, they cannot prove that different warnings would have caused her to change her behavior.

The third cause of action asserted by plaintiffs is for what's called a breach of express warranty. Here plaintiffs claim that Ms. Knight was injured by Pradaxa because Pradaxa was not as represented. To establish this claim, the plaintiffs must prove these elements:

First, that Ms. Knight purchased Pradaxa;

Second, that BI made a statement of fact to Ms. Knight related to Pradaxa;

Third, that Pradaxa did not perform as stated;

Fourth, that Ms. Knight was injured;

And, last, that the failure of Pradaxa to be as

represented was a substantial factor in causing Ms. Knight's injury, including death.

Formal words such as "warranty" or "guarantee" are not required to create an express warranty. It is not necessary for BI specifically to have intended to create a warranty. However, a warranty is not created if BI simply gave its opinion of or recommendation regarding Pradaxa.

The fourth cause of action is for breach of implied warranty. Here plaintiffs claim what Ms. Knight was injured by Pradaxa because the product did not have the quality that a buyer would expect. To establish this claim, the plaintiff must prove these elements:

First, that Ms. Knight purchased the Pradaxa;

Second, that at the time of purchase, BI was in the business of selling Pradaxa;

Third, that Pradaxa was not fit for the ordinary purposes for which such goods are used;

And, fourth, Ms. Knight was injured;

And, last, that the failure of Pradaxa to have the expected quality was a substantial factor in causing Ms. Knight's injury, including death.

The fifth cause of action is for fraud. To prevail on a claim for fraud, the following must prove the following -- the plaintiffs must prove the following:

First, that BI committed an act that was material and

false;

Second, that Ms. Knight relied on that act;

Third, that Ms. Knight was justified under the circumstances in relying upon it;

And, last, that Ms. Knight was damaged because she relied on it.

For their fraud claim plaintiffs must prove each of these elements by clear and convincing evidence which is a higher standard of proof than preponderance or greater weight of the evidence.

The last thing I want to explain the law concerning what are called punitive damages.

Now, although I'm explaining the law of punitive damages, it does not mean that I have any opinion on whether punitive damages should be awarded. That decision is yours alone. You are not required to award punitive damages.

If you award the plaintiffs compensatory damages to compensate for Ms. Knight's injury or death, then you may also award them punitive damages. You may not award punitive damages if you do not first find that plaintiffs are entitled to compensatory damages.

As a general proposition, the purposes of punitive damages are, first, to punish a wrongdoer for conduct that has harmed another party; and, second, to discourage a wrongdoer and others from acting in the same way in the

future.

Therefore, punitive damages are damages that are awarded to punish and deter wrongdoers. Punitive damages are in addition to any damages you award to compensate a party for injuries or loss.

Punitive damages may be awarded where you find by clear and convincing evidence that BI acted with actual malice toward Mrs. Knight or that BI acted with a conscious, reckless, and outrageous indifference to the health, safety, and welfare of others.

Clear and convincing evidence is proof that produces in your mind a firm belief or conviction that actual malice, or that conscious, reckless, and outrageous indifference to the health, safety, and welfare of others has been established.

Actual malice may be found where you find that BI acted with a state of mind shown by conduct that was intended to or was substantially certain to injure Ms. Knight without any just cause or excuse.

If you find that BI took steps to warn about the risks associated with Pradaxa, you may consider these efforts when deciding whether BI acted with any actual malice.

Therefore, if you find from the evidence that BI committed a wrongful act with actual malice toward Ms. Knight or acted with a conscious, reckless, or outrageous indifference to the health, safety, and welfare of others,

then you may decide that punitive damages should be awarded.

Now, at this time in your deliberations you should only decide if plaintiffs have met their burden to show that punitive damages should be awarded. You should not try to choose or determine an amount of punitive damages at this time.

But, remember, you are not required to award punitive damages. And any punitive damages that are awarded would be in addition to any damages necessary to compensate plaintiffs for Mrs. Knight's injury or death.

Now, if you decide that the plaintiffs, Claude Richard Knight and Claudia Stevens individually and as personal representatives of the estate of Betty Knight, deceased, have proven that the defendant is legally responsible for her injuries, you may reasonably compensate plaintiffs for any harm that Betty Knight suffered.

The purpose of awarding damages like this is to compensate a person who has been injured or harmed as fully and completely as possible. Damages that are speculative cannot be recovered.

However, the mere fact that damages may be difficult to determine should not cause you to refuse to award them where the right to such damages has been proven.

You may award the following specific items of damage if they have been proven by a greater weight of the evidence:

First, Betty Knight's past physical pain and suffering, mental anguish, disfigurement, emotional distress, or loss of enjoyment of life.

There is no rule or set method for deciding the amount of these damages. The amount of these damages is left to the discretion of the jury to decide what is fair and just. You must use your judgment to decide a reasonable amount based on the evidence and your common sense.

Betty Knight's past reduction of capability to perform as a whole person, to recover for this plaintiffs must prove that the injury deprived or reduced Betty Knight's ability to participate in her customary activities and resulted in the loss of enjoyment of life.

Again, there's no set rule or method to decide this type of damage. The amount of this damage, if any, is left to the discretion of the jury to decide what is fair and just. You must use your judgment to decide a reasonable amount based on the evidence and your common sense.

Also, Betty Knight who -- her representatives have alleged a claim for reimbursement or compensation for past medical expenses. To recover damages for past medical expenses, plaintiffs must prove the reasonable cost of reasonably necessary medical care that Betty Knight received.

The medical bills introduced in this case are to be

considered reasonable and necessary unless you find that the defendant has proven that these medical bills were not reasonable in amount or necessary for medical care for Betty Knight.

If Betty Knight had a physical or emotional condition that was aggravated or made worse by the defendant's wrongful conduct, you may award damages that will reasonably and fairly compensate plaintiffs for the aggravation or worsening of Betty Knight's pre-existing condition.

If you find that Betty Knight was more susceptible to injury than a normal person, you may still award damages to plaintiffs for the injuries caused by the defendant even if a normal, healthy person would not have suffered similar injury.

Now, if you decide the plaintiffs have proven that BI is legally responsible for the death of Betty -- of Mrs. Knight, then you may award these damages. These are called wrongful death damages.

You may award plaintiffs as the administrators of Betty Knight's estate damages for expenses reasonably incurred as a result of her death.

These expenses incurred may include damages such as reasonable funeral expenses, reasonable hospital and medical expenses related to the injuries suffered by Ms. Knight that resulted in her death, and any other expenses reasonably

incurred as a result of the wrongful conduct that resulted in Ms. Knight's death.

You may award damages to the administrators -- that's the two individual plaintiffs -- that you find are fair and just to reasonably compensate Claude Knight and Claudia Stevens, Ms. Knight's children. You will decide the amount of any award to be distributed, if any, to each of these persons.

In making any award of damages to be distributed to each of these persons, you may consider the sorrow, mental anguish, and solace suffered as a result of Ms. Knight's death. This loss may include loss of society, companionship, comfort, guidance, kindly offices, and advice of Ms. Knight.

Second, compensation for any conscious pain and suffering that Ms. Knight suffered between the time she was injured and the time of her death.

To award damages for pain and suffering, there must be evidence that Ms. Knight was conscious of the pain and suffering suffered -- suffering prior to her death. Where there is no evidence that Ms. Knight consciously perceived pain and suffering, no damages for pain and suffering should be awarded.

With the exception of some brief closing instructions, those are the Court's instructions as to the law you're to

apply. Now the parties will be providing their closing statements.

Plaintiffs bear the burden of proof as to their claim, so plaintiffs will do an opening portion of closing argument. The defendant may respond to that. And then plaintiffs will have a final brief reply or rebuttal period.

At that point I've got literally about one minute of further instructions before you go back and begin your deliberations.

With that, for the plaintiff.

MR. CHILDERS: Thank you, Your Honor.

Good morning, ladies and gentlemen.

I want to start first by thanking you. You've been here for almost three weeks now and I know that's not easy for anybody, especially when you're trying to work and take care of your family.

And on behalf of myself, on behalf of Rick and Claudia and Neal and the rest of the folks that have supported us in bringing this trial to you, I thank you from the bottom of my heart.

We heard just yesterday from Dr. Crossley. You'll remember Dr. Crossley. And he told us Pradaxa is not the right drug for all patients. There are some patients it's not right for.

And you'll remember just last week we heard from

Dr. Ashhab. Pradaxa was not the right medicine, not the right anticoagulant drug for Betty Knight.

You've heard a lot about the fact that Betty was prescribed the 75-milligram dose of Pradaxa. That's what she took.

You've heard a lot about the fact that that dose was never tested in humans. You've heard that it was never tested -- Pradaxa itself was never tested in severe kidney impaired patients like Betty Knight. We all agree on that. That's no dispute.

Before they sold that drug to her, before they told her doctors, "This drug is okay for Betty Knight," they never tested it in any patient like Betty Knight. And they never tested the 75-milligram dose at all.

What we also agree on is that if you are a patient like Betty Knight who has severe kidney impairment -- I should say severe, I'm sorry -- and is also taking Coreg, a P-gp inhibitor, you should avoid Pradaxa. We know that now. Unfortunately, the company didn't tell Betty or her doctors that information when she was prescribed Pradaxa.

What we also agree on; there's no reversal agent for Pradaxa. You get a bleed, you've got to wait it out. If you're on warfarin, they can give you Vitamin K. They can give you fresh frozen plasma. And they can stop the bleed much quicker.

What we also agree on, the risk of a GI bleed. A bleed just like Ms. Knight had is 50 percent higher for any patient on Pradaxa than it is on warfarin.

We also agree when you have a lower GI bleed, which is what Betty had, you're three times more likely to have a lower GI bleed on Pradaxa than on warfarin. That information was not provided to Betty Knight or to her doctor.

What we also agree on, we went around and around on this. Betty Knight did not bleed when she was on triple therapy, Plavix, aspirin and Coumadin.

You'll recall a couple days ago Dr. Shami got up on the stand in direct and said, "Well, she never took those three drugs together." Remember that?

And then I got up on cross and said, "Well, let's look at the record." She did. She took triple therapy on Coumadin in 2009, didn't bleed.

We also agree Betty Knight had a severe GI bleed, a life-threatening GI bleed on triple therapy when she was on Pradaxa. Why did that happen? Triple therapy is dangerous. I agree. It's a dangerous combination of medicine.

But when you have a patient like Betty and you put them on triple therapy with Pradaxa, they're three times more likely to have a lower GI bleed like she did than if she would have been on warfarin, three times more likely.

We also agree Betty Knight's family requested that she be switched to Pradaxa from warfarin for convenience. They didn't know about the risks, about the dangers of Pradaxa to a patient like Betty.

They knew that warfarin had worked for her. She hadn't had a stroke. She hadn't had a bleed. But it wasn't the most convenient drug. They saw the ad and they asked for Pradaxa and it was prescribed to her.

We also agree there's no dispute Pradaxa contributed to Betty's severe GI bleed. Dr. Crossley told you that. He's their paid expert, their paid witness. Yes, Pradaxa contributed to the bleed.

Dr. Shami got up here the day before and said, "I don't have any opinion of any drug she was taking caused, contributed, had anything to do with the bleed." Do you recall that?

And she's a gastroenterologist. They hired a gastroenterologist to come in here and tell you this woman had a gastrointestinal bleed and, "I don't have any opinion if any of these blood-thinning medications she was on had anything to do with it, not one way or the other. I haven't even decided."

We also agree Boehringer never sent a "dear doctor" letter, one of these letters that says, "Hey, healthcare professional, hey doctor, hey nurse, we have changed the

label. There's really important information we put in there. We want to bring this to your attention."

No question, they never sent a letter like that to Betty's doctors or any doctor in the country saying if a patient like Betty comes to you with severe renal impairment and they're taking Coreg or some other P-gp inhibitor, Pradaxa is not the medicine for them. They never did that.

We all agree that Boehringer never sent any warnings, any warnings to Betty other than the Medication Guide. We're going to talk about that in a little bit. But that is clearly the only information that was ever provided directly to Betty by Boehringer.

And we all agree that Betty was more debilitated after her bleed than she was before. You saw I kind of went back and forth with Dr. Crossley yesterday, but he had to admit to me that he told me that when I took his deposition.

He said, "Yeah, she, she -- I think she was already debilitated, but you're right. She was more debilitated after the bleed," no question.

We're to the point now in the trial where you have to decide all of the issues. And the thing that you're going to do that with is the verdict form. This is the verdict form that you'll have to take back in the jury room and decide all the questions.

And the very first part of it is plaintiffs' claims and

it's liability. Liability means if they do something wrong that harmed the plaintiff.

And what we have here are five different claims. And I want to go through each one of them with you so you can see how we believe the evidence has proven each of those claims in this case.

The first one is called strict liability failure to warn. The Judge just read you a jury charge. We call that jury charge, jury instructions. I believe you'll have those back with you in the jury room. Look at them.

What it tells you very specifically, Boehringer -- in two different places in the jury charge it tells you Boehringer as a manufacturer of prescription drugs has a duty to warn patients directly about the risks of Pradaxa.

I expect they will get up here and tell you, "We told our doctors all kinds of stuff or at least they should have known about all kinds of stuff." That's not the law in West Virginia.

Their duty is to tell Betty Knight all of this information so she can make the choice. "Yes, I want to take that medication and take those risks," or, "No, it's just not worth it to me."

You heard evidence from multiple witnesses on deposition, as well as Dr. Plunkett came live.

Dr. Friedman you'll recall worked -- these four folks

on either side of Dr. Plunkett all work for Boehringer.

Dr. Friedman you'll recall told us, "Patients with severe renal kidney impairment, yeah, we didn't include those in our clinical trials."

And then he said something that is just mind-boggling. He, the guy who works at Boehringer, the scientist who helped develop this drug, said, "I don't know if Pradaxa is safe and effective for a patient with severe kidney impairment." He said that. Yet, they sold that drug to Betty and didn't tell her that information.

And he also told you that when patients have certain risk factors, we expect they're going to have a higher Pradaxa level in their blood, and that, that can be dangerous.

He also told you when you add all those risk factors together, they compound each other. They get bigger and bigger. He said, "We don't actually put that information in the label. We don't tell doctors how to figure out what the bleed risk is going to be when you have multiple factors."

We heard from Michelle Kliewer. Her job is to talk to the FDA, tell them what Boehringer knows about this drug. She said, "It's our duty, Boehringer's duty to ensure Pradaxa warnings are complete and accurate."

The Judge told you the same thing. That is Boehringer's duty. That's not the FDA's duty. Boehringer,

as the manufacturer of the drug, has the legal duty to make sure that the warnings that they provide are complete and accurate the entire time that drug is sold.

Michelle Kliewer also told you that they haven't told the FDA that they know how to identify patients who are at a higher risk by using a particular blood test. They didn't share that information with them.

And she told you that Boehringer didn't tell the FDA about the internal analysis they did of their own data in the RE-LY trial that showed, hey, if we actually do this blood testing, we'll probably make this drug safer for all the patients who take it. They never told them that.

You heard from Dr. Brueckmann who told us that the risk of bleed is tied to the Pradaxa level in the body. The more you have, the more your risk of bleed.

She also told you that's not in the U.S. label. We don't specifically tell doctors here that the more Pradaxa you have, the more likely you are to bleed. We do tell doctors in the rest of the world that. We just don't tell them here in the United States.

She also told you something very important. She said -- and my friend Neal asked her a question about whether or not Boehringer has a duty to minimize certain risks. And she said in response Boehringer has a duty to minimize any risk, any risk to patients.

You heard from Dr. Van Ryn. She told you again you increase the level of Pradaxa in a patient's blood, you increase their bleed risk.

And she even said, "I'm, I'm a scientist and I think -- I work on this drug. I think it's not a bad idea to check that blood level every six months or every year." But the company's mantra, the company's position is you never have to check it.

The scientist who works on the drug says it's a good idea. The company mantra is don't tell anybody that. You tell people that, they're not going to prescribe our drug.

And then you heard from Dr. Plunkett. Dr. Plunkett was the only person who came into this courtroom who is an FDA expert. Boehringer didn't bring you one of those. And she told you about the duties that any drug company has and that Boehringer specifically has.

She told you how they failed to properly warn doctors and patients about the true risk of bleed with Pradaxa. And she told you that none of this information was ever communicated to Betty Knight or to Rick Knight or to Claudia Stevens, none of it.

And she also told you that the first four items on here weren't even communicated to Betty's doctor when she was prescribed Pradaxa. There's the chart. They never warned Betty of any of these things. That's their duty. It's not

a hard duty.

And I want to make sure you guys understand. Just because someone is injured, that doesn't make a case. Drug companies have a duty. They have to tell patients what they know about their drug, what the safety issues are, what the benefits are so patients can make informed decisions. Yes, I want to take it. No, I don't.

And when they don't do that, that is where liability comes in. You have to. It's not hard. They know this information. It's not hard to tell people things you know. But they didn't do it.

Again, we just talked about this. The Judge told you -- sorry. The responsibility for the label is Boehringer's. It's not the FDA's. Don't, don't be confused. Don't be tricked by them coming up and saying FDA has approved this label every time we've asked for it. They've never asked for the approval of the things that we've talked about in this courtroom.

It's not FDA's job to make sure that label is accurate. It's Boehringer's. That's the law.

The Judge also told you about the burden that we have as plaintiffs on our claims. And I'll read it to you again and we accept that burden and I want to make sure you understand that burden the way I do.

And it is: Plaintiffs must prove each element of their

claim by the greater weight of the evidence. The greater weight of the evidence means evidence that you believe outweighs the evidence opposed to it. It means the evidence that is more persuasive or convincing.

This is not a criminal case. Our burden is not to prove beyond a reasonable doubt. We come in and we start even. We're on one side. Boehringer is on the other. I'm going to call this side ours because I'm pointing at my friend Neal. If we go this much (indicating), we win. That's the burden.

Now, I believe we've gone a lot farther than that, but we don't have to tip the scales so that it falls over. We only have to have the greater weight of the evidence. It's very important that you remember that when you're deciding the issues in this case.

And I believe based on the information we've provided to you, we've met that burden on strict liability failure to warn.

And, so, when you get back in the jury room and you're looking at the verdict form, you should check "yes" on direct liability failure to warn.

Our next claim is negligent failure to warn, the same as. It's just a different claim using different standards.

The Judge read to you specifically what those standards are. I'm not going to repeat them all to you. Suffice it

to say it is the same evidence that we rely on for both of those claims; failure to warn, failure to warn.

You saw yesterday that Betty Knight read the information that was provided to her with her first Pradaxa prescription. That Pradaxa prescription came before any of this information was in the physician label. And it came, obviously, because none of this has ever been in the Medication Guide, without any of that information to her directly.

You saw the record. Dr. Crossley walked through it with me. Not only did she read it herself, the home health person came in there and made sure she verbalized to them. That means she told them, "I understand what you've told me about this information you just read to me from the information I got from the pharmacy."

And we know what information she got from the pharmacy because we have the label and we have the Medication Guide. It didn't tell her any of these things.

We also know that, again, Betty didn't warn -- excuse me. Boehringer didn't warn Betty's doctors about these things. Now, they'll tell you, "Well, we told them there was a reversal agent." Yeah. It was buried in the overdosage section on who knows what page in Section 10 of the label.

And what happened after that? They moved that

information right up to the risk of bleed part of the label, the warning where it should have been so doctors actually see it. They don't just find out once a patient is overdosed, "Oh, gosh, I don't have a reversal agent. I didn't know that."

They didn't have that information in the label when Betty started taking Pradaxa when it was prescribed to her.

This is directly out of the defendant's own papers that they published in 2014 after Betty passed away. And they, they own this. They know this.

When you give Pradaxa to two different patients, one could have a huge amount in their blood. One could have a low amount in their blood.

And how do we figure out how much it is? Well, we just kind of guess. We look at how your kidneys are doing. And how do we look at how your kidneys are doing? We use an estimate for that. It's not a direct measurement either.

And, so, we kind of guess how much Pradaxa you have in your blood because we don't want to tell people how to find out exactly how much Pradaxa you have in your blood by just simply doing a blood test.

You heard from Dr. Plunkett. She drew this -- I think she called it Mr. Bill. She drew this character to show you how the Pradaxa gets in the body, how little of it actually gets used by your body as an anticoagulant, and then how

it's sent through your GI tract, your intestines.

And as it's going through there, it's actually being activated locally which means -- and this is just a bizarre thing. It's going through your GI tract causing places, just random places, especially if there's a sore or a lesion, to be over-anticoagulated.

She also explained to us this concept. This isn't a hard concept. Any anticoagulant, there's a balance. If you have to too much, you're going to bleed. If you don't have enough, it doesn't help you.

I think you heard from the, the defense yesterday that, well, we have all kinds of medicines we give people and they don't all have to be measured and balanced. No, that's true, absolutely. But those aren't anticoagulants. When you have a drug that is to thin a patient's blood, let her know how much they have in their system. If you don't, it's dangerous. How do we know that? Their own paper again. As Pradaxa levels go up, bleed risk increases.

And here's the part that's just, again, hard to believe, but it's what they know. Stroke risk remains essentially the same. And what that means, if you get to a certain point, a certain level of Pradaxa in your blood, that's the maximum amount of stroke protection you're going to get.

It doesn't matter if you double it, triple it,

quadruple it. You're not going to have better stroke protection. Every increase you have in the level makes your risk of bleed higher and higher and higher and higher. That is why doctors need to know how to measure Pradaxa levels in their patients.

We saw Neal and Dr. Plunkett showed us that in this same paper. This is right out of that paper, the Boehringer paper about how bleeds and stroke are tied or are not tied to plasma concentration or blood levels.

You heard from Dr. Friedman. Yeah, you can measure the blood level. If you do that, you can identify people who are going to absorb more of this drug. They're going to have more of it in their blood. Yeah, we can do that.

You heard from Dr. Brueckmann. She said, "I believe it's important to have the opportunity to measure."

You heard from Dr. Friedman again. He said, "I think that would be helpful for physicians if they knew that."

And then you heard from Dr. Van Ryn who said, "Not a bad idea to check it every six months or so."

So what does BI tell doctors here? You don't need to do that. You don't need to assess Pradaxa levels. It says that in the label.

What do they tell doctors in other countries? If you do assess the label, you can identify patients who are at an excessive bleed risk.

In the U.S. what do they tell them? Well, tell you how to measure the blood level. You saw me go around and around with Dr. Crossley yesterday. He said this test, this aPTT, that doesn't measure your Pradaxa level. That's right. It doesn't.

So what do they tell -- but that's what they tell doctors here in the U.S. to use. What do they tell doctors in the rest of the world? Use a different test, the one that measures the Pradaxa level.

You recall yesterday he and I went around and around on that. He said that's not measuring plasma concentration. And I had to actually show him the words twice until he finally agreed with me. "Yeah, that's what it says."

That's what they tell doctors everywhere else, just not here. The U.S. label doesn't tell doctors how to -- I'm sorry. It doesn't even tell them that a patient can have an excessive high exposure for Pradaxa.

And we know that that message is getting across. You know how we know that? What did Dr. Abdelgaber say when I asked him in his deposition, "You understand a patient can have too much Pradaxa in their blood and be over-anticoagulated." He said, "I never heard that. What are you talking about?"

Because they don't tell the doctors that in the United States. They tell them exactly what the excessive level is

in these other countries and how to measure it. In the U.S. Boehringer doesn't tell doctors that female patients are going to have a higher Pradaxa level in their blood just because they're female. They tell doctors everywhere else in the world those females are going to have 30 percent more Pradaxa in their blood.

Neither one of these doctors knew. You heard from them. They testified, "I didn't know there was a Pradaxa level that's too high. If I had known, if they told me how to measure blood levels, yeah, I'd do that. Any doctor would do that."

Dr. Brueckmann -- we already talked about this. They have an obligation to limit any risk they can. And they can limit that risk just by telling doctors and patients the truth, but they don't.

So negligent failure to warn, I believe yet again we've more than tipped the scales on that claim. And when you get to the jury room, you should check "yes" as well.

We have additional claims, breach of express warranty. Now, what does that mean? A lot of words. It means they told her it was safe for her and it wasn't.

And you'll see down here that they don't have to be formal words like "warranty" or "guaranteeing this to create an express warranty." And they don't even have to intend to. If you tell a patient a drug is safe for them and it's

not, you have breached an express warranty.

So what did they do? They gave her a Medication Guide. And what did they say in that Medication Guide right up at the top? What is the most important information I need to know about Pradaxa?

We're going to tell you, we're going to tell you right here this is the most important information you need to know about Pradaxa. And you know what wasn't included? Any of this, not one bit of it. Express warranty was made.

Claudia saw an ad that said this is a more convenient medicine for a patient. It didn't say not a patient like Betty. It said for any AFib patient. They called the doctor. They made an appointment. They got a prescription. And when they filled that prescription, they got the Medication Guide and she read it. Not only did she read it, she sat down with a home healthcare worker and made sure they went through every bit of it and she understood it.

And when she was told by that Medication Guide what was the most important thing to know, it wasn't any of these things that both Rick and Claudia have told you would have kept them from ever asking for this drug to be given to their mother.

Breach of express warranty? Yeah. I believe we've met our burden.

The next claim that we have is called breach of implied

warranty; again, sort of like the failure to warn claims. It's, it's basically the same. They sold a product to the patient that was supposed to work a certain way and it didn't. It's not safe for her. It's a good medicine for some people. It's not a safe medicine for a patient like Betty Knight, but they didn't tell her that. Again, the same issues.

So when you get to breach of implied warranty, you should check "yes."

We have another claim. And that next claim we have is called fraud. That's what it sounds like. You misrepresented. You said things that weren't true or you omitted things that you should have told someone that were vitally important to them, and it was material and false.

Ms. Knight relied on it. She was justified in relying on it. That's important. They told her it was a medication that was safe for her. They told her doctors it was a medication that was safe for her. She -- any patient would be justified in relying on that, so she did and she was damaged. She had a severe life-threatening gastrointestinal bleed that we've all talked about.

Here's the fraud. They all know it's important to be able to check Pradaxa blood levels. Every one of them says, yeah, you should do that.

Why don't they do it? Because they had a plan from

before the drug was ever approved. And that plan was no monitoring. Our mantra, our mantra is no monitoring. If we have monitoring, it's going to undermine our efforts to compete with the other NOACs.

You heard Dr. Crossley yesterday. There's two other drugs in this class that he used. If Pradaxa had monitoring where they don't, nobody would be prescribing Pradaxa to their patients.

What else did we hear from the defendant? We know there's this range that's safe and effective. A little too early. This is after the drug is on the market. This is, this is just before Betty Knight starts taking it. This is August of 2011.

From a marketing point of view, we better not start talking about a target plasma range. We don't want to talk about people checking Pradaxa blood levels. Not from a scientific point of view, not from a safety point of view, not from a medical point of view, from a marketing point of view that decision was made by Boehringer.

Why? Because it would be a competitive disadvantage versus -- that's Xarelto, Rivaroxaban, and that's Eliquis, Apixaban. And then what? We've got to change part of our story.

Well, that's a common theme with this company I think you've seen in this trial. They've changed their story a

few times.

She never took triple therapy with Coumadin. Oh, wait. Yes, she did. She had all kinds of high aPTT values before. Oh, I'm sorry. Those weren't actually aPTT values. The story changes constantly.

What did Michelle Kliewer tell us? She's the FDA regulatory person who works for this company. Marketing should not influence the content of the Pradaxa label. That's right. We saw that it did and it does to this day and that hurt Betty Knight.

So when we get to the -- when you get to the next section, fraud, again, I believe we've met our burden.

Okay. Now, this is important too. It says right here if you answered "yes" to any of questions five -- you may disagree with me. You may say, "I don't think they've proved express warranty. I don't even know what express warranty means."

And I'll be honest with you. It's not an easy thing to understand for me.

But if you answer "yes" to any one of those five questions or five of those five questions or two of those five questions or three, then you move on to the next section of the verdict form that's called causation, legal causation.

And there's a very straightforward question: Did

plaintiffs prove absent BI's wrongful conduct in any one of those five, any one of those five Betty Knight would not have taken Pradaxa? That's the question you have to answer.

If they had warned her about it, if they hadn't told her it was safe when it wasn't, if they hadn't misrepresented to her and her doctors the fact that you should monitor, then we've proven that. That's legal causation. That's the first step of legal causation.

You know what happened. Claudia saw a TV ad. You heard Dr. Crossley yesterday. "When a patient comes to me and asks for a particular NOAC drug, Pradaxa, Eliquis, Xarelto, whichever one it is, I'm pretty sure they heard that on a television commercial."

That's what happened here. You saw the documents. Betty had an appointment on the 17th of October. Rick called that morning, "Hey, we want to talk to the doctor about changing this Coumadin."

And when they got to the doctor, what did they say? "We want to replace Coumadin with the new medication Pradaxa." "Why?" "Well, we saw an ad that said it's safe and more convenient for Betty." That sounds great. But they didn't know it's not safe for Betty.

And you heard from Dr. MacFarland. She said Betty didn't have a stroke or a bleed while she was on warfarin. We switched her based on a request. And she said patients

often request drugs after they see TV ads. She knew about Pradaxa.

She said if they had provided instructions for measuring the Pradaxa level, she would have done it. If she had done that, Betty would have come right back off of Pradaxa because it's not a drug for her.

I suspect you're going to hear from the defendant, well, yeah, you know, she filled out this form for insurance that says the reason for the switch was because Betty was sub- and supratherapeutic. And you'll recall Dr. Shami liked that term a lot better than "over-anticoagulated" and that's fine.

But think about that. If Dr. MacFarland was told Betty's insurance is not going to cover Pradaxa, sorry, and she really wanted her to be on Pradaxa because the family asked for it and she wrote on the insurance form the reason for switch is patient saw a TV ad and wants to try it, do you think the insurance company would have said "yes"? Pradaxa costs hundreds of dollars a month. She had to write that on there or it wouldn't have been approved.

You saw the Medication Guide. You know that the information that they got didn't tell them any of these things. They didn't get any other information. They didn't know any of these things. We know she read it. Not only did she read it, she went over it with her home healthcare

provider.

And how about this? Their own paid witness. You would think they would have coordinated a little better. They bring in two paid witnesses, one from Virginia and one from Tennessee.

And the first one who, by the way, doesn't prescribe Pradaxa, doesn't prescribe any anticoagulants said warfarin just didn't work for her. She was absolute resolute in that.

And then the cardiologist came yesterday and he said it would have been appropriate for her to stay on warfarin. That's right. It would have been just fine for her to stay on warfarin. Is it less convenient? Yes. What's, what's more important, convenience or safety? Safety.

What else did Dr. Crossley tell you? Coreg is absolutely 100 percent a P-gp inhibitor drug. And I have to confess to you I'd never heard the term P-gp inhibitor until I started working on this case. I had no idea drugs worked that way, but they do.

And what did he say? Coreg is a commonly prescribed drug, especially in AFib patients.

And then when I asked him how he knew that Coreg was a P-gp inhibitor drug, he said he'd seen some lists and knew about it. And then I showed him the Coreg label, the drug label.

So if a doctor has that label while they're prescribing Pradaxa, are they going to know it's a P-gp inhibitor? No. You know why? Coreg is an old drug. They don't change labels in old drugs very often. You know why? Because it costs money, and generic drug companies don't like to spend money.

But the more important part, the Pradaxa label doesn't mention Coreg anywhere. It tells the doctor, "Don't give Pradaxa to a patient like Betty Knight if she's taking a P-gp inhibitor," but it doesn't list for them one that is commonly prescribed, especially in the patients who get Pradaxa.

You've heard from Claudia. She said, "If I had known any of these things, I would not have asked for my mom to switch. I didn't know that. I thought this was going to be a good medicine for her. Why would I put my mom on a drug that's never been tested in patients like her? Why would I put her on a drug that the drug company knows is not safe for her? And, hey, if she's more likely to have a GI bleed on this drug, I don't want her to be on that."

You heard the same from Rick. They did this together as a family. And they weren't told the truth.

So when you get to the next phase, legal causation, you should check "yes." And if BI -- if any of those five things hadn't -- let me rephrase that. I believe all five

of those items in the first part are what led Betty Knight to be on Pradaxa. But any one of them is enough.

And certainly it was because of the information she was and was not given about Pradaxa that she switched to Pradaxa. That's why she was taking it. And if she had known this, they never would have asked for it and she wouldn't have been on it.

Next, there's another part, there's another part on the verdict form for legal causation and that is did plaintiffs prove that Pradaxa proximately caused Betty Knight's injuries.

Proximately caused. That's a word we only use in court. I don't know any other place where you use it. And, so, luckily for us, the Judge has jury instructions where he defines it and he gives them to you so that you can understand it. Some day I hope I can understand it better, but I've got to be honest with you. I've been doing this for 20 years and I still have a hard time understanding proximate cause.

The most important part of that charge that I believe you should look to is there can be more than one proximate cause of an injury, more than one. That's what we have here.

She was on triple therapy. And you heard from Dr. Crossley himself. Pradaxa was part of what caused her to

bleed.

You heard from Dr. Ashhab. It was part of what caused her to bleed. And it was a substantial cause of it.

And not only that, when she had been on triple therapy before with Coumadin, this didn't happen. So even if you say, well, I don't think Plavix (verbatim) triggered the bleed, that doesn't mean plaintiffs lose. There's more than one proximate cause.

Pradaxa, according to both plaintiffs' experts and the defense experts, was part of that cause.

You heard from Dr. Abdelgaber. "Did you feel at any time during her admission her life was in danger, her life was in danger from the GI bleed?" And he said unequivocally, "That's why I admitted her to the hospital. I thought her life was in danger."

She was on Pradaxa at the time of that life-threatening bleed, not warfarin. Again, she had been on the combination with warfarin before, Coumadin and warfarin, same drug. She didn't have this problem.

And we know there's no diagnosis of her ever having a GI bleed while she was on the warfarin. Dr. Ashhab went through all the records. Dr. Shami went through all the records. Dr. Crossley went through all the records, 4,000 plus pages which I hate to tell you guys you're going to have back there with you, 4,000 pages. It's like a giant

box over here. We may have already given that to the Court. They looked at all those.

And you heard when I asked Dr. Shami, "Are you talking about this particular hospitalization, November, 2008?" "Yep."

We went through painstakingly every place in that record and I said, "Where does it say she had a GI bleed?" "Well, it doesn't but she had dark stools." That's what she said.

I said, "Well, let's look at where it says dark stools." "Well, actually it says she had some diarrhea that was a little darker than usual."

That is the only thing that she relied on to say Betty Knight had a GI bleed. The diagnoses, huh-uh, they don't say that. She had anemia. She's got kidney failure. That happens. You have to get transfusions sometimes.

What did Dr. MacFarland say? She treated Betty Knight for years. She never had a bleed or a stroke while she was on warfarin that I'm aware of.

We're still on proximate cause here. Okay. So I want you to keep this in mind. Again, greater weight of the evidence. Nobody disagrees. Betty is more likely to have a GI bleed on Pradaxa than she would have been on warfarin. How much more? 50 percent for any GI bleed. We agree on that. For a lower GI bleed, three times more likely to have

on Pradaxa than on warfarin.

You recall that Neal and Dr. Plunkett went through the information that was in this article written by Boehringer to show you're three times more likely to have a lower GI bleed on Pradaxa than you are on warfarin.

What did Dr. Crossley say about whether or not Pradaxa was the proximate cause? First of all, he said the GI bleed was a big blow to Betty Knight. I don't know if you recall that. It stuck out to me. And he said unequivocally Pradaxa contributed to her GI bleed, no doubt.

And then this was interesting because I thought I heard him saying that he had an opinion on direct exam. But when I showed him that's not what he said in his deposition, he had to agree with me.

And I -- hopefully I didn't annoy you all by having to go back and forth with him on that deposition so many times, but it's important to get the truth.

And what he said was, "I actually don't have an opinion on whether the bleed contributed to her death. I'm going to defer that to some other doctors. I'm not an expert in that."

But we heard from other doctors. Dr. Abdelgaber said she never recovered. She never recovered from that GI bleed. And who else? Dr. Ashhab. He said the same thing. She didn't recover. She had no reserve; the straw that

broke the camel's back.

And you'll recall he said, "It doesn't matter how heavy that straw is. It's just that last straw that makes it happen."

And when you have a patient like Betty Knight, she's had a heart attack before. And she had this non-Q wave -- I can't recall exactly how it's termed -- heart attack. That's a lesser dangerous heart attack than the Q wave heart attack. That's what Dr. Crossley told us.

She would not have died from that heart attack if she had a reserve, if she hadn't been so debilitated from the bleed.

So when you get to, when you get to question 7, did plaintiffs prove that Pradaxa proximately cause Betty Knight's injuries -- and I want to make this clear too.

There's two issues here. Did it cause the bleed injuries? That's one. Did it cause the death? That's two.

You may not agree with me on those two things. You don't have to. Either one of those I think you should check "yes."

Next is legal causation for the death. Again, this goes to proximate cause. Again, proximate cause, a cause, not the cause, a cause, caused or contributed to her death.

And what did we see in the records? She didn't bounce back. July 12th, the day after her birthday, by the way,

and I think you recall what we heard about that. She had a heart attack in April and Rick had a birthday in May. She went to the birthday party. She was doing well.

She had a GI bleed. Then she had her own birthday, July 11th, 2013. She was so debilitated, they couldn't even get together for dinner. They'd never done that before. That had never happened in this family before. They always celebrated her birthday together.

You saw another hospitalization June 22nd, weak and debilitated, again referencing the bleed, same hospitalization. She's just not getting better.

Three days later, not getting better.

August 14th, debility.

August 23rd, debility.

The GI bleed. We've talked enough about what happened during that GI bleed, but we know that she had a life-threatening GI bleed. She had four units of blood. Her hemoglobin dropped dangerously down to 6.

What did Dr. Shami tell us? GI bleed? Well, you should be in the hospital two or three days and gone. Very, very unusual for her to send a GI bleed patient to skilled nursing.

Not two or three days for Betty Knight. It's three weeks, three weeks. That's not a normal hospitalization even from the defense's own expert.

And she told us, "If that patient comes in on warfarin, yeah, we can, we can give them reversal agents. We can give them fresh frozen plasma. We can give them Vitamin K. In fact, I do that routinely. That's what we do."

And then the part that -- again, I scratch my head at several things in this trial, but she doesn't even prescribe Pradaxa. And she came in and tried to tell you all about how safe it is and how good it is and how the label adequately warns doctors about a drug she has never even prescribed.

And then we see the discharge from skilled nursing. Debility, general debility. She did have various medical problems and we're not trying to run away from that. But this was the straw that broke the camel's back, the severe gastrointestinal blood loss, had her in the hospital and skilled nursing for three weeks.

And here's the death certificate. And I suspect they're going to get up again and say, "Dr. Abdelgaber wrote this and he didn't include GI bleed or Pradaxa." You heard that several times from them. They're right.

And I have to be honest with you. When I first saw this death certificate, I had serious doubts about this case too. But I made a promise to Rick and to Claudia that I would investigate thoroughly.

And, so, we went and talked to Dr. Abdelgaber. We

didn't just look at the paper. We went and took his deposition and said, "Tell me about the bleed and how that might have affected this."

And what did he say? When he's asked himself, not just on a piece of paper, he said declined after the GI bleed, never really recovered, and that she came back in the hospital multiple times after the May hospitalization each time complaining she wasn't getting better. And then she passed away the last time she came in. That's from his own words.

And it -- you recall Dr. Shami yesterday said, well, he only treated her for a couple months. He didn't even see all the records. And I had to point out to her that by the time we got to his deposition, not the time when he signed the death certificate -- I agree. He probably hadn't seen most of the records. By the time we got to his deposition three years later, he had seen them all. And he said she never got better. The bleed she never really recovered from.

Okay. So when you get to question 8, did plaintiffs prove that Pradaxa proximately caused Betty Knight's death, again, greater weight of the evidence; a cause, a cause, not the cause, did it contribute to her death. You should check "yes."

And if you do that, then you move on to what's called

damages. This is the hardest part for me to talk about. It's the hardest part for me to comprehend. What are the damages that you award to a patient, to a person who's been injured?

We don't have a perfect civil legal system, but this is what we have. When people are injured by somebody else's conduct, the only thing we can do is award them money damages. We can't bring Betty back. We can't give anymore time to Rick and Claudia with their mother. It's not possible. All we can do in our system is award money damages.

And, so, what you'll see is two different kinds of damages. The first one is for the injuries. This is the injuries, not the death. West Virginia law provides for both of those. There's economic damages and there's non-economic damages.

Economic damages are the medical bills. And you heard from the Judge the medical bills introduced in this case are to be considered reasonable and necessary. That means what she incurred, she had to incur. And she's entitled -- the estate is entitled to get those back.

And the only way you cannot find them reasonable and necessary is if Boehringer has proven to you that those bills weren't reasonable or necessary for her medical care. They didn't put on one iota of evidence to try to refute

that. I assume that means they agree those bills are reasonable and necessary.

And you'll have the bills back there with you. It's Exhibits 2005, 2006 and 2007. And you'll see that the total of those medical bills from St. Mary's Medical Center, home health, and the Huntington Internal Medicine group, which is Dr. Abdelgaber, was $99,444.73. That's the economic damages that were suffered. That's, that's the easy part.

Here's the hard part. Pain and suffering. What's pain and suffering? Betty Knight's pain and suffering during the time between when she was injured and she died. And it's her reduction of her capability to function as a whole person.

There's no formula for this. There are suggestions we can make and I can suggest to you. Some juries look to the medical bills as a starting point. You base the pain and suffering on some multiple of the medical bills. That happens. I'm not telling you you have to do that. I'm just suggesting to you I've seen it done many times.

Whether her pain and suffering was two times what her medical bills are, three times, five times, 10 times, that's not up to me. That is up to you.

But I will tell you the amount of money that she incurred for medical expenses pales in comparison to the pain and suffering she had during those last few months of

her life. She couldn't even celebrate her own birthday with her kids.

How do we know about this pain and suffering? We heard from Rick. She had a toilet bowl full of blood when he got to her house on May 20th. He took her to the hospital. She was there for three weeks, didn't go home for three weeks from a bleed that Dr. Shami said most people should get out of the hospital in two or three days.

I don't know if you've ever spent time in a hospital, but I can tell you one day in the hospital is excruciating. She was there for three weeks.

That's her at skilled nursing. That's where she had to meet her great-grandson, not at her house, not Claudia's house, at the skilled nursing facility.

So when it comes to damages -- excuse me, I'm sorry -- I would suggest to you that for economic damages it's the medical bills. Again, that's easy, $99,444.73.

Non-economic damages, that is up to you. I've given you some suggestions. Use them. Don't use them. Use what you think is fair. That's all that the Knight family wants, fair, reasonable, fair.

And then we move on to wrongful death damages. And you'll see here on that verdict form just below that if you find that her death was caused by Pradaxa, or proximately caused, excuse me, that it was a cause of her death, then

you can award wrongful death damages.

Again, there's no formula for that. The Judge will tell you what things -- he's already told you, excuse me, things that you can consider when you're trying to come up with what are wrongful death damages. You'll have the, the jury instructions back there with you.

But most importantly -- first of all, part of that is medical bills. That's already taken care of. There's not another set of medical bills and you shouldn't award medical bills twice. That, that wouldn't be reasonable.

But what I think is important is there are claims to be awarded damages through here to Rick and Claudia. That's the way the law works in West Virginia. And I'll read this to you again. The Judge has already read it to you.

That you can award -- when you are making your award of damages to Rick and Claudia, because they're the beneficiaries of the wrongful death claim, you can consider the sorrow, mental anguish, and solace suffered as a result of Ms. Knight's death. This may include loss of society, companionship, comfort, guidance, kindly offices, and advice of Betty Knight.

You heard from Rick and Claudia both. They saw Betty multiple times a week. They talked to her every day. She was with them at every holiday. She was with them on vacations. She was part of their lives. She was a mom.

She was a friend.

And, yes, she was 84 years old. But wrongful death damages are awarded whether you take away 50 years of someone's life or 50 hours of someone's life. You've taken away from them something that shouldn't have been taken away. That's how you measure it.

Now, all I would suggest to you there is whatever you awarded for the personal injury economic damages, I would say that's a starting point. Wrongful death damages are significantly more than that. And, again, that formula is up to you to decide. I just told you that part. You'll see that back there again.

You can also award conscious pain and suffering for the time that Betty was injured to her death. But, again, we've already talked about that as part of her economic damages for the injury, so that shouldn't be awarded twice.

And this -- for wrongful death this is what we're talking about. This is the family. That's Betty with her grandson. That's Betty dancing with her grandson at his wedding. She won't get to do that with her other grandchildren.

That's Betty with her great-grandchildren. She won't see them graduate from high school. She won't see them get married.

That's Betty at the *We Are Marshall* premier with Rick

and Claudia.

That's Betty's birthday, not in 2013 because they couldn't celebrate that year, but that's Betty's birthday a year or two before.

And that is what this case is really all about. Betty, Rick, Claudia, a family unit, a tight family unit. That's how you -- those are the things you need to consider when trying to determine damages for wrongful death.

The last thing as far as damages is something called punitive damages. You don't have to -- if you decide that Boehringer's conduct was reckless and outrageous with indifference to the health, safety, and welfare of others, then we've proven punitive damages.

Punitive damages are not to award the Knight family. That's to punish Boehringer, to tell them, "Don't come to West Virginia and lie to patients. Tell patients the truth."

And, so, this is about Boehringer's conduct. It's awarded to punish and deter. Don't do it again. Don't do this again. That's what it says to a defendant.

Boehringer, this is all about them. Marketing should not influence the content of the label. They agree. We saw in the fraud part of this presentation marketing, marketing, marketing.

Even though the world is crying -- this is an internal

document from their own scientist, "The world is crying for this information." Don't give it to them.

As far as what they told the FDA, we never recommended to the FDA you should measure Pradaxa levels. It would be helpful to avoid excessive high exposure. No. We just tell doctors everywhere else in the world that, not here.

We never told them there's a specific number of a blood level that would be a cutoff value. Don't go over that amount. No, we never told the FDA that.

We never told the FDA there's a number, don't, don't go past it because it increases the risk of bleeding and it makes that increase too much. No, didn't tell the FDA that.

And why? It's a goal. Sell as much Pradaxa as possible.

Why didn't they tell Betty Knight the truth? You saw this in my opening statement. There's a huge potential market here. Millions of people have atrial fibrillation. It requires life-long treatment. This was to be a blockbuster billion-dollar drug as long as there was no requirement that you monitor the patient's blood levels. That was an absolute necessity to make this drug a success.

This is what I showed you at the beginning of the case. This is what we expect we'll hear from the defense. And that is what we did hear from the defense.

Betty Knight was sick, very sick. Yeah, I agree. But

you will see in the instructions and Judge, Judge Chambers has already told you if Betty Knight had a physical or emotional condition that was aggravated or made worse by Boehringer's wrongful conduct, you may award damages that will reasonably and fairly compensate plaintiffs for the aggravation or worsening of the pre-existing condition.

If you find that Betty Knight was more susceptible to injury than a normal person, she's sick, she's not a normal person for these purposes, then you may still award damages to plaintiffs for the injuries caused by Boehringer even if a normal, healthy person would not have suffered similar injuries.

You got to keep that in mind when they come in here and say she was sick, sick, sick. That is how they -- that's the person they market this drug to, elderly atrial fibrillation patients.

Don't sell a drug to a sick patient population and then say it's not our fault when we hurt them because they were already sick. You can't do that. And that's why the law says if you make them worse, you're on the hook for it.

They'll say Betty Knight, Betty Knight had to be anticoagulated. Yeah. What did Dr. Crossley tell you? Warfarin was appropriate for her.

What did Dr. MacFarland tell you? She didn't bleed or have a stroke when she was on warfarin. She could have

stayed on warfarin.

They'll tell you FDA approved Pradaxa. And they did based on the information that Boehringer gave them, not on any test the FDA did itself.

They'll tell you Pradaxa -- or they told you Pradaxa is better than warfarin. We have no data to prove that for patients like Betty Knight or for this dose. You've got a computer model that they ran. That is not proof that Pradaxa is better.

And then they told you Plavix caused this bleed. They brought you Dr. Shami who after on direct she said all kinds of stuff about the medicine and had to admit, "I actually don't have any opinion on that."

They brought you Dr. Crossley who said, well, Pradaxa was a cause of the bleed. It contributed to the bleed. Remember the proximate cause. It could be more than one thing.

And you'll recall that Betty had taken Plavix before when she was on Coumadin. She did not have a bleed. Remember those things.

Before I sit down and defense counsel gets up, I want to leave you with two questions. Hopefully they'll answer to you.

First one: Why did they not tell Betty Knight any of these five things? If they have a good, reasonable

explanation, I have yet to hear it.

The second thing: Why not tell doctors in this country how to test Pradaxa blood levels and what level is too high just like you tell doctors in the rest of the world? Why don't you do that? Because I haven't heard an explanation for that either.

I'm going to sit down now. I'm going to have a few minutes after Ms. Jones is done. Hopefully she'll answer those questions for you.

Thank you.

THE COURT: All right. We're going to take a brief recess before we move to the defendant's closing argument. So we'll take about 10 minutes or whenever you're ready. My Court Security Officer will be there. Just let him know.

Please remember that you've only heard the plaintiffs' closing argument, not the defendant's. So don't discuss the case or these closings. Wait until you've heard everything.

Thank you. We'll reconvene in about 10 minutes. We'll stand in brief recess.

(Recess taken at 11:47 a.m.)

(Back on the record at 11:55 a.m.)

THE COURT: All right. Are we ready?

MS. JONES: We are, Your Honor.

THE COURT: Let's bring the jury in.

Mr. Childers, you have about 15 minutes left.

MR. CHILDERS: Thank you, Your Honor.

(Jury present.)

THE COURT: All right. We're ready to proceed. You may be seated.

Closing statement.

MS. JONES: Thank you, Your Honor. And good afternoon to all of you.

I'm very happy to have a chance to speak with you again, and I want to start where Mr. Childers started. I thank you all for your time and your attention. We've had a couple of long weekends, and I will tell you sometimes jurors don't come back after three- or four-day weekends. So we are very grateful for everything you've done to serve as jurors in this case.

I told you at the very beginning of the case that losing a loved one is a tough thing, it's a difficult thing. And as we've gone through the evidence, it occurs to me that it's also a universal thing. It is one of those things where we all share the experience of losing someone who is dear to us. And I suspect there's not a single person in this

courtroom who hasn't heard the testimony of the plaintiffs and related to some of what they had to say.

What stuck in my memory was when Mr. Knight was testifying, and he said, you know, you're never ready. No matter what has happened with someone, you're never ready to lose someone you love. And so if you have felt sympathy or related to what you heard, we don't ask you not to feel that way. Our case does not depend on you not having sympathy for the Knight family. Our case depends on you all doing exactly what you committed to at the beginning of this case three weeks ago and what the judge has instructed you to do, to make a decision based on the evidence. That's all we ask.

And that's really important. It is the way our system works. It's the only way we know that our system works for every single one of us, is that folks like you take time out of your lives, and you take an oath, and you say I'm going to make a decision based on the evidence.

Now we recognize you all did not pick us, we picked each and every one of you. And the reason that we did that is because we were confident that you would each keep that commitment to decide the case based on the evidence, in the same way that we know that you keep your commitments in your personal relationships, in your profession fields of endeavor, as members of this community, as citizens of this country. That's why we chose each and every one of you.

Now one thing that Mr. Childers said at some point in his closing was it can be tough -- it's important to get to the truth. It is important, we agree on that. One question that occurred to me when he said that was how on Earth do you do that in a case like this when there's been so much evidence, and the lawyers have gone back and forth so much with the witnesses, have said things that seem to be different on both sides of the case.

Let me suggest to you what the judge has already instructed you on, that you rely on the evidence that is more persuasive or more convincing. In a case like this, where it's all about Mrs. Knight, her experience on warfarin, her experience on Pradaxa, what happened with her in 2013, the most persuasive, the most convincing evidence is not bullet points on a slide. It's not summaries of what lawyers say something meant from either of us. You don't have to take our word for anything. The most persuasive, the most convincing evidence is what did Ms. Knight's doctors say. At the time, in the real world, before there was a lawsuit, before any of us lawyers got involved and started asking folks questions, what did they say? What decisions did they make? What did the medical records, many of which you have now seen, reflect about what they thought was going on with Mrs. Knight?

And I told you at the beginning of the case, I invited you, take everything we say and compare it to the evidence.

Make sure that you're pressure-testing what you've been told by counsel against the evidence. And let me give you an example of why that is really important in this case.

In opening statements, you were told this by counsel. You'll hear from Dr. Abdelgaber. That was Mrs. Knight's primary care doctor. He'll say she just didn't bounce back, she didn't recover like I had hoped she would, and then she passed away. That's what you were told in opening, and then you saw the evidence.

This is Exhibit 9001. This is the death certificate for Mrs. Knight from September of 2013. What Dr. Abdelgaber said in September of 2013 was not that he thought that she had a GI bleed, and she just never recovered. What he said was I think she passed away because she had a heart attack, because she had serious coronary disease, which you've now heard described Dr. Crossley, and that's what led to her passing.

Now what struck me as we got to the end of the case yesterday, and still sticks with me now, is if we hadn't shown you this document, if we had not moved it into evidence, I'm not sure you ever would have seen it. Counsel for plaintiffs did not show the death certificate for Mrs. Knight to a single witness in the case.

Dr. Ashhab testified for an hour and a half, maybe two hours on direct about what he thought about what had happened with Mrs. Knight. He was never asked about the death

certificate. He was never asked how do you square what you said to what her primary care doctor said at the time about what led to her passing? He was never asked that question.

Mr. Lewis, you might remember, got up on cross-examination. He was the one who first entered that document into evidence and asked Dr. Ashhab, have you seen this? Have you ever considered this document?

Do you remember what Dr. Ashhab said? He said, I don't think so. I'm not sure that I've ever seen it. He had testified to a reasonable degree of medical certainty about what happened with Mrs. Knight, and he never considered what is arguably the most important piece of what we describe as contemporaneous, and that just means real time, evidence on the subject of what led to her passing.

And Mr. Childers, he has some time left over. They have the burden of proof, and so he gets to stand back up and talk some more. And he may tell you, he may explain why it was that they never showed that document to their only causation medical expert. He may tell you why they didn't even show the document to Dr. Crossley or to Dr. Shami.

You never heard that they thought the document was incorrect, that it was inaccurate. Even Dr. Ashhab, he said, yeah, that is what he says. He never said it was incomplete. He never said it was wrong. Mr. Childers might explain that for you for the first time on the last day of presentations by

the parties. But this is what I mean when I say take what we say and compare it to the evidence.

Now I'm going to walk through some of that evidence in a slightly different order. You have seen the verdict form already, and I'm actually going to start with the questions that are in section B.7. and B.8., what we've generally described as medical causation. Those are the questions that Mr. Childers walked through with you on whether or not plaintiffs had proved that Pradaxa caused either Mrs. Knight's bleed or caused her passing in September of 2013.

And I told you at the beginning of the case that that was really a central issue. That even though they have five claims, they are really all failure to warn claims. But even though they only have five claims, for every single one of those claims, they have to prove causation on both of those points. If you're not persuaded of that by a preponderance of the evidence, you have to answer no as to each and every one of those claims, and so I want to start by talking about those issues first.

Mrs. Knight, I told you at the beginning of the case, it's awfully hard to understand what happened with her in September of 2013 without understanding what had been going on with her for years. And you've seen in those medical records -- bless you, Your Honor. And you've seen in those medical records, Mrs. Knight had a number of chronic, very

serious medical conditions that her doctors were helping her with.

And at some point in the trial, I think Mr. Childers said, well, she was more than just her medical records, she was a person, and that's absolutely true. You see that in the pictures of her and her family, her grandkids and her great grandkids. She was a person, but this is a case about her medical care and her medical treatment. Their claims are about her medical care and her medical experience.

And I'm going to tell you, there was more to her medical history than the fact that she had a GI bleed in May of 2013. There was a fuller story there that wasn't shared with you during the plaintiffs' case.

For example, you were told, I think over and over again, that before Mrs. Knight ever had a GI bleed, she had hospitalizations, but she always bounced back. That became almost like a catch phrase during the course of the trial. Dr. Ashhab used that phrase. He never showed you any of the medical records relating to how Mrs. Knight actually did when she was -- prior to when she was on Pradaxa, before she had a GI bleed. These are those records, hospitalization after hospitalization from various things. That is not bouncing back.

And after some of those hospitalizations, just to give you an example, back in 2008, she had a nine-day stay in the

hospital for acute respiratory failure. Then after that, she had to spend eight days in a skilled nursing facility. And even after that, she still reported issues with her diabetes.

Here's another example. In October of 2011, Mrs. Knight had to go to the hospital because they thought she had had a heart attack. She had that elevated troponin that you heard about from Dr. Crossley. And after that, she had to spend two weeks in a skilled nursing unit, all before she ever had a GI bleed. She didn't bounce back from these things.

And that doesn't mean that she was a bad person or that her doctors were bad doctors. I think looking at her records you can tell that her doctors, folks right here in Huntington, were doing the very best that they could to try to take care of her. It doesn't mean that her children, Mr. Knight and Ms. Stevens, didn't care about her and didn't try to do what they could to help her. But she had a complex medical history, which you heard very little about in the course of the plaintiffs' case.

One of the things that you didn't really hear about until just yesterday was the fact that Mrs. Knight had very serious coronary artery disease. And that's just a function of the way the trial goes. The plaintiff gets to put their case on first, so we didn't have a chance to call our cardiology expert until later in the case. But you then got to hear what was going on with Mrs. Knight well before she

ever took Pradaxa, well before she ever had a GI bleed.

Remember Dr. Crossley got up, and he showed you on that big board of the heart. He described what was going on with Mrs. Knight, that she had blockages all over the left side of her heart, she had blockages on the right side of her heart. It was so serious that her doctors had to place two metal stents in her heart because they were trying so desperately to try to protect her from having a heart attack.

That's the full picture of Mrs. Knight's medical history. And the reason that we talked about it, the reason that we spent so much time about it with the only expert cardiologist you heard from in the case is because this is what Mrs. Knight's doctors said led to her passing in 2013. That's why we spent time on it. That's why we thought you were entitled to see and know about that evidence.

And you heard from Dr. Crossley, even in patients who have coronary artery disease and they don't have a heart attack, they can still have incredibly serious symptoms. And you see that all throughout Mrs. Knight's medical records, congestive heart failure, coronary disease. You saw repeated references of her having chest pain, cardiomyopathy, that disease of the heart muscle that impairs its ability to function. All of this before she ever had issues with Pradaxa, before she ever had a GI bleed, this was her state of living. This was her state of being for a long, long time.

This is what her doctors were trying to help her with.

Now you've also heard that Mrs. Knight took Pradaxa, and she took Pradaxa because she was a patient who had atrial fibrillation and was at a very high risk of having a stroke. I don't think there has been any question in the case that Mrs. Knight had to be anticoagulated. The reason Mr. Childers knew I was going to say that is because that's the evidence. Those are the facts in the case.

Mrs. Knight was on Pradaxa for two years, from October of 2011 until September of 2013. And one of the things I think is really important that you know, just based on the records -- and this isn't disputed either -- Pradaxa worked for Mrs. Knight.

You've heard about warranty claims that have been made in this case, warranty claims that require a showing that somehow the product didn't work the way that it was promised. The product worked. Mrs. Knight was told this is a medicine that is prescribed to keep you from having blood clots. That's exactly what it did. For two years, she was well managed on the medicine. That is the evidence relating to her experience with Pradaxa.

Now even though Mrs. Knight's atrial fibrillation was being dealt with, her stroke risk was being dealt with, her heart disease was continuing to progress. And in April of 2013, you've now seen this evidence, Mrs. Knight had a heart

attack in April of 2013.

And I almost thought I heard Mr. Childers say, well, that wasn't a serious thing. That wasn't a serious event. And you can test that claim against your own common sense, against your own life experience, and you can test it against the actual medical records in the case.

Her doctors went back into her vessels to look to see what was going on, and they found additional 90-percent, 95-percent blockage in her vessels. And when they actually wrote in the medical records whether this was something that had been there before or whether it was new, they said these are new blockages. This is something else that has occurred since she had her stents in 2008 and 2009.

She had progressive disease, not because she did anything wrong. We know now, based on the evidence, that she wasn't able to take statins. She had an allergic reaction to statins that caused her to have muscle pain, and so it was hard for her doctors to be able to treat her as effectively for that reason. That wasn't her fault, but it meant that her coronary artery disease was able to progress more than it might have otherwise.

That was the thing that changed for Mrs. Knight in April of 2013. Not that she had been on Pradaxa, and she had a problem. It was the fact that she had a heart attack, and her doctors had to place two additional stents in two more

vessels of her heart because they trying to keep those vessels open so that she wouldn't have a heart attack. And that created that challenge, what you heard described by I think a couple of the doctors as a rock and a hard place, where you have a patient who needs to be protected from stroke, and so they're on an anticoagulant, and you also need to protect that patient from developing a clot on that metal stent that's been placed in the heart.

Dr. Crossley, again the only expert cardiologist you heard from -- they didn't bring a cardiologist to talk to you -- he's treated lots of these patients, and he has told you that's a delicate, difficult situation. Those patients are at an increased risk of bleeding no matter what.

That's why the Medication Guide, the Medication Guide for patients says specifically your risk of bleeding might be higher if you're on Pradaxa and you're on Plavix and you're on aspirin. We warn about that. That's why the labeling for doctors said one of the risks of bleeding is if you're also on antiplatelet agents. That's our warning.

You heard claims about malice and fraud and lying to people. This is what the company told patients and told doctors about the risks related to the situation that Mrs. Knight found herself in in April of 2013. And there's no evidence in the case that her doctors didn't fully appreciate that risk for Mrs. Knight at that time.

Now, there was a lot of back and forth with words like trigger, what triggered the bleed, what caused the bleed, what was the source of the bleed. These are the facts. Mrs. Knight was on Pradaxa for 19 months. She had no bleeds. She had no strokes. Even Dr. Ashhab acknowledged she was on that medicine for a long time, and she had no problems. There is not even a whisper in the medical records that she was having an issue with Pradaxa.

But after she had a heart attack, she had her stents placed, and they added Plavix to her existing medicine regimen of Pradaxa and aspirin, she was on triple therapy. And about a month after that happened, she had a GI bleed.

Now, you've been told a lot about what Dr. Shami said or didn't say or what Dr. Crossley said or didn't say, and you can sort that out in your own judgment. But look at what her doctors said about what they believed had led to Mrs. Knight's bleed. This is a record from around that time where it specifically says she was put on Plavix, which probably triggered her bleed.

And you can also draw reasonable conclusions based on how her doctor responded after she had that GI bleed. It was stopped within a day. That's also not disputed. We didn't fuss about that. They managed her bleed, they got it under control, and then they put her back on Pradaxa.

This is another record where you can see her doctors

said they didn't want her back on Plavix because they were concerned about the GI bleed. But they said, I don't think that the Pradaxa could be held because she's got a risk of clots. She's at a very high stroke risk, and they put her back on Pradaxa. She continued on that medicine until September of 2013. She had no issues, no bleeding, no stroke.

Now you have to use your own common sense in understanding the chronology here. Even if you put to the side what all of the witnesses you saw here said, look at what her doctors did at the time. If her doctors believed that Pradaxa had caused her to have what they have described as a severe life-threatening bleed, if they believed that, do you think that they would have put her back on Pradaxa and let her stay on that medicine? No. No, that's a reasonable conclusion that you can draw from the evidence.

Now you've been shown a portion of the jury instruction on this issue, and I want to say something very clearly. If you're on an anticoagulant, you have an increased risk of bleeding. That's the case whether you're on Pradaxa or warfarin or Xarelto or Eliquis. That is no -- no question, that is the case. And you've been told, well, if Plavix triggered it, that's okay because Pradaxa can be another proximate cause, and that's what the instruction says.

The part of the instruction that wasn't read to you was this one: Boehringer's conduct proximately caused the

injury if the conduct, in the natural and probable sequence of events, brought about the injury, and the injury would not have happened without the conduct.

Now what does that mean on Mrs. Knight's facts, in her situation? What they have told you is if Mrs. Knight had just been kept on warfarin, then she wouldn't have had that bleed. That's what they've told you. That's what they have tried to persuade you. That is the basis for their claim that Pradaxa was a proximate cause. And you will have the instruction in the back where the judge has told you they have to demonstrate that the injury would not have happened. And in her circumstance, that means if she hadn't been on Pradaxa, but was on some other anticoagulant. There's no evidence of that.

For one thing, every gastroenterologist told you that that lesion in Mrs. Knight's colon, what you heard described as an AVM or an arteriovenous malformation, that can bleed whether you're on an anticoagulant or you're not on an anticoagulant. Every single GI doctor, including Dr. Ashhab, told you that. Those are common in older people. Whether you're on a blood thinner or not on a blood thinner, they're prone to bleeding because those vessels are all twisted up, and they are more fragile than they would normally be. That's the evidence.

The other thing is that by April of 2013, Mrs. Knight would have been a very high risk warfarin patient. Dr.

Ashhab, during his cross-examination, was shown the labeling for warfarin. You will have this back in the jury room with you, and you see right there in the hemorrhage section, it says coumadin or warfarin can cause major bleeding or fatal bleeding, and it goes on to list 13 risk factors for bleeding. Mrs. Knight, by April of 2013, had 10 of those.

Now some of those risk factors were risk factors that would have applied with Pradaxa as well. She was older. She had renal problems. Those are things that increase your risk whichever drug you are on. But the label for warfarin also tells you, if you had a high intensity of anticoagulation, that means that your INR levels have been high, what you saw in the evidence, that increases your risk.

If you have highly variable INRs, that factor No. 3 -- you saw that zigzag chart throughout the course of the case -- that can increase your risk. They tell you at the very bottom of the list, if you've had a long duration of warfarin therapy, that can increase your risk of bleeding on the medicine. By April of 2013, Mrs. Knight would have been a very high risk patient to have on a medicine like warfarin.

And even Dr. Ashhab, on cross-examination, he had to agree these risk factors would have only gotten worse with time. She would have gotten older, and her bleed risk would have gone up. She would have been on the medicine longer, and her risk of bleeding on warfarin would have gone up. That is

the evidence, including evidence that even their own expert confirmed.

Now one thing that you've heard is, well, Mrs. Knight was on Plavix and aspirin and warfarin back in 2009, and she didn't bleed, so that means she wouldn't have bled in 2013. And you heard Dr. Crossley's response to that. That is speculation at best. And actually what we know is that Plavix and aspirin present the same issues for warfarin as they do for Pradaxa.

This, again, is the labeling for warfarin, the doctor labeling. And this specifically mentions both aspirin and clopidogrel, which is also known as Plavix, as drugs that can increase the bleeding risk for patients who are also on warfarin.

You remember yesterday, Dr. Crossley and I went through that paper, I think the lead author was called Ganz, and it was a study that people had done to look at, from the the RE-LY study, how did patients do when they were on triple therapy with warfarin versus triple therapy with Pradaxa. You remember what Dr. Crossley told you? They didn't see any difference in the results. People did the same, they had equivalent numbers of bleeding, except for brain bleeding where Pradaxa patients did better. Otherwise, there was no indication that the outcomes were different for patients on warfarin versus patients who were on Pradaxa and had triple

therapy.

Now they spent a lot of time in the course of the case talking about this statement, that Mrs. Knight never had a GI bleed while she was on warfarin. We spent a lot of time on that issue, and there's a reason for that. And that's because their medical records, record after record after record, that report her doctors used at the time in the real world, before lawyers were ever involved, saying things like she has been on coumadin for atrial fibrillation, but this was stopped because of her chronic bleed. That is the evidence. She had not been on coumadin because of a GI bleed.

Another record from Dr. Gunnalaugsson in May of 2009, she has had bad GI bleeds in the past. Those were the records. And a lot of the time that we spent was spent with counsel trying to explain away the plain language in the document.

And there was almost a suggestion yesterday during Dr. Crossley's cross-examination that maybe Dr. Gunnalaugsson had said, oh, I got it wrong, that maybe at his deposition he said something different. Let me tell you, if Dr. Gunnalaugsson had testified at his deposition those records were wrong, I don't really think she had a GI bleed, you would have seen that testimony. They didn't play that testimony to you. There was no evidence that Dr. Gunnalaugsson believed anything other than what he wrote in his records, that he believed that

she had had GI bleeds on warfarin. And you saw him making decisions about her care based on his concerns about her having another bleed while she was on warfarin.

And even Dr. Ashhab, remember Mr. Lewis cross-examined him on the topic of what he looked at to testify with such certainty that Mrs. Knight had never had a bleed on warfarin. You remember this? He said, actually there were three years of warfarin records that he had never considered, that he had never evaluated. I think Mr. Childers said, oh, well, Dr. Ashhab looked at all the records. His sworn testimony was for 2005, 2006, 2007, all the years when we know that Mrs. Knight was on warfarin, he never looked at those records. He never confirmed that there wasn't evidence of a GI bleed in those records. And you're entitled, you're entitled to more than speculation from a paid expert who didn't look at everything that he would need to to give you reliable evidence and opinion on that topic.

Now the other thing that you heard is that Mrs. Knight was somehow at some special risk on Pradaxa because she was over-anticoagulated. And Mr. Childers told you, you'll have all of those medical records back there with you, there is not a single one where a doctor who cared for her said I think she might be over-anticoagulated. No doctor ever said that about Mrs. Knight when she had her GI bleed in April of 2013.

And even the evidence that Dr. Ashhab points to

doesn't support this theory of what you heard described by counsel as over-anticoagulation. He pointed to three separate things, her patient factors, the fact that she was a woman, that she had bad kidneys. He pointed to the fact that she had an elevated aPTT. And he pointed to the fact that she had lost a lot of blood during her GI bleed in the spring of 2013.

Let's talk about the first one. During her entire use of the medicine Pradaxa, Mrs. Knight had all of those patient factors that Dr. Ashhab talked about. She was on Coreg. She was on aspirin. She was a woman. She was older. She was in her -- moving towards her 80s, in her early 80s. She had impaired kidney function. She had all of these factors. She never had an issue on the medicine except when she was placed on Plavix. She was otherwise fine. There is no reason to believe based on the evidence that Mrs. Knight was ever over-anticoagulated because of her patient factors. That is not evidence of over-anticoagulation.

He also pointed to the fact that she had gotten this aPTT reading. An aPTT is just a measure of how quickly your blood is clotting. So if you are on a blood thinner, it will take longer. That is just the way it works medically.

And you saw here her range was 47. Her number was 47. She was within a reference range of 25 to 37. As it turns out, all of these doctors testified you would expect a patient who was on an anticoagulant to have a higher aPTT level. That

is what you would expect because anticoagulants slow down the rate at which your body actually creates a clot. That is the -- that's how they're supposed to work.

And then the last thing he cited is the amount of blood. And you heard from Dr. Shami, there is no evidence to suggest that the amount of blood that Mrs. Knight might have lost in April of 2013 -- excuse me -- May of 2013, that that signaled over-anticoagulation. And certainly you don't see anywhere in her medical records, not a single doctor, not a single nurse, not a single person who treated her, laid hand on her in real time say I think this is a patient who is over-anticoagulated.

And, again, just use your common sense, what you know about medical care. If her doctors believed that, that she was over-anticoagulated on Pradaxa, would they have put her back on the medicine and allowed her to continue on the medicine until she passed away in September of 2013? The evidence doesn't support that theory.

And actually what you saw when Dr. Ashhab was actually pushed on this testimony -- this was his direct testimony. Did you form an opinion on whether or not she was over-anticoagulated? He said, I did, I think she was over-anticoagulated.

And then Mr. Lewis got up, and he asked Dr. Ashhab: Your conclusion that Mrs. Knight was over-anticoagulated at

the time of a bleed that had apparently started several days before, the fact is you're guessing, right? That was the question.

Do you remember what his answer was? Yes. Full stop, no explanation. Yes, I'm guessing. That is not evidence. You can't reach a verdict based on a guess. You're entitled to more than just guesswork when you have to reach an important decision in the case like this one.

Now after Mrs. Knight's bleed was treated, you heard that she had a colonoscopy, and they went in and they evaluated what was going on. Her doctors treated her bleed the same way that the Pradaxa label for doctors said that that's what you need to do.

And you heard a lot about this was a life-threatening bleed, this was a severe bleed. And we don't quibble with the idea that this was a serious event that required medical attention. That is not a dispute in the case. But it was treated. Within a day of her coming to the hospital, they had gotten that bleed under control, just like the label recommends.

First of all, stop Pradaxa. The label says discontinue treatment with Pradaxa.

They transfused blood. The label says initiate appropriate clinical support, give blood. That's how you treat GI bleeds.

They performed a colonoscopy. You saw the deposition testimony of Dr. Huh, a doctor right here in Huntington, who did her colonoscopy. That is what the label says to do, investigate the source of the bleeding.

And then they evaluated her aPTT to figure out what might have been going on with respect to the medicine, and that's what the label says, too. When it's necessary, you can use aPTT to assess her anticoagulant activity in patients on Pradaxa. Her bleed was managed in exactly the way that the label recommends, and it was successfully managed.

Even Dr. Ashhab, this was his testimony. He was asked: Within 24 of presenting to Dr. Huh, Mrs. Knight was stabilized, and her AVM was treated, correct? He said yes. He said that I would view that as a successful treatment of an AVM. That bleed was stopped. It was stopped fully in May of 2013.

Now at the same time Mrs. Knight had other medical issues. She had a heart attack, as you know, in April of 2013, and she continued to have heart issues as time went on. Now there is a reason that, even after a long trial, I spent time with Dr. Crossley to talk through each of those records of her care in the summer of 2013. That's because I think you are entitled to know exactly what her doctor said about what was going on with her at that time.

And you were shown this slide during counsel's

argument earlier. This is what you were shown. You may remember it. They are all of these little clips from the records, and I'm going to encourage each and every one of you to go and back locate these records and look at them.

Not a single one of those records says we think that her debility, her weakness, the fact she's not doing well was caused by her GI bleed. Not one of those records says that. And there's a reason that they didn't put that on the slide because it's not anywhere in those medical records.

Dr. Crossley told you, when he testified yesterday, that the reason that she was continuing to have issues was not because of her GI bleed, but because she had a long history of having heart disease and symptoms from heart disease. And after her GI bleed, the symptoms that she had were entirely consistent with the symptoms that she had had before. They were entirely consistent with progressive, worsening heart disease. That's what you heard from Dr. Crossley, the only cardiologist who treats patients with this condition. That is what he told you, and that's what her medical records reflect.

What you have been told is that if only -- instead of putting her on Pradaxa in October of 2013, if only they put her on warfarin, just they just continued that prescription on warfarin, then all of that stuff would have been different. There's no evidence of that. The medical records don't support it. Dr. Ashhab never really came out and said that.

There is no evidence of that.

The evidence is that Mrs. Knight unfortunately had very serious heart disease, and that continued right up until she passed in September of 2013. And you know that because that's what Dr. Ashhab [verbatim] said. That's what he said when he had to fill out the death certificate.

And every doctor who testified in front of you today -- throughout the course of the trial said when I have to fill out a death certificate, it's a serious thing. I try to be accurate. It's a legal document. I try to be complete. There was never any suggestion in the course of the trial that Dr. Abdelgaber had done anything other than that.

And what I think I heard in plaintiffs' counsel's closing argument was, well, we deposed him later, many years later, and he thinks something different now. That's not what he testified to. What he testified to was it's just as likely that her heart attack was the reason that she had all of those issues in the summer of 2013.

He never -- he was never shown the death certificate at his deposition. Counsel didn't show him the death certificate and say do you still believe this is true? And you weren't shown any testimony from Dr. Abdelgaber suggesting that he believed anything other than what he wrote in this legal document in September of 2013, at the time, where he said Mrs. Knight had a heart attack.

She had an acute myocardial infarction, and that was because she had coronary artery disease, atherosclerotic coronory artery disease that had been so serious that she had to have metal stents placed in the vessels of her heart. And that was caused by high cholesterol, high cholesterol that was hard for her doctors to treat because they weren't able to use statins.

And when Dr. Abdelgaber had an opportunity in this document, 9001, to say here are the other things I think might have been involved, he didn't mention Pradaxa. He didn't mention the GI bleed. He said -- he mentioned the same chronic issues we've already talked about, congestive heart failure, kidney disease, dementia, hypertension. He didn't say a thing about Pradaxa.

That is entirely consistent, by the way, with all of the medical records in that summer of 2013. There was a death summary that we talked about with Dr. Crossley. They don't even mention the fact that she had a GI bleed. Her doctors believed that what led to her passing was the fact that she had a heart attack, and that's what you heard from both of our experts, Dr. Shami and Dr. Crossley, the one cardiologist you heard from in the case.

The one doctor who told you something different was Dr. Ashhab. And you learned -- during his cross-examination, Dr. Ashhab was asked, have you seen the death certificate?

Have you looked at what is arguably the most important piece of evidence in the case on this issue? I'm not sure. He couldn't even be certain that he reviewed that evidence. You're entitled to more than that when you're being told that Pradaxa was the reason that Mrs. Knight passed away, when they have a burden to prove that to you.

Even the plaintiffs, when they were asked -- and you may remember Mr. Lewis didn't ask a lot of questions on cross-examination of Ms. Stevens and Mr. Knight. He might have asked five questions total. But even when they were asked about their discussions with the doctors who cared for their mother, doctors they'd been interacting with -- you heard that they were very involved in her medical care.

They were asked, with respect to the GI bleed, do you recall any doctor ever coming to you and saying that was caused by Pradaxa? This was Mr. Knight's testimony. He answered very directly.

Did any doctor in the real world ever tell me that Pradaxa caused it? No, sir. They didn't tell me that.

Ms. Stevens was asked a similar question: To the best of your recollection, did any of the doctors that treated your mom tell you that Pradaxa caused her decline or her death, any of them? No. They were candid about that.

In the real world, in real time, before lawyers got involved in all of this, that's what her doctors said, that

she had died from a heart attack caused by coronary artery disease. You've not been pointed to any evidence, any real world evidence, real time evidence to suggest anything contrary to that. And so your answer on both of those questions that you saw in the verdict form, question B.7. and B.8., should both be no as to Mrs. Knight's injuries, her bleed in the spring of 2013, and as to her death in the fall of 2013.

I now want to turn to this issue of warnings. And you were told I think by Mr. Childers at the beginning of the case that even though there are five claims, they're all basically failure to warn claims. And I'm going to address them kind of collectively in that way and offer some responses to the questions that he raised for what the company did and why the company did it.

You have been told that in West Virginia, a company like BI has an obligation to warn patients directly, and that is absolutely true. And the company does that in something known as the Medication Guide. You've now seen that in the evidence. And that is a document that is FDA-approved. It's regulated. The structure, the content, the FDA has to approve all of that.

The other thing that is important about the Medication Guide is that it's written for patients. It's a patient friendly document, and it's written for all patients. If you

give Pradaxa to a hundred patients, a thousand patients, a hundred thousand patients, the goal is that you create something that is straightforward and direct and communicates to patients the danger of the medicine.

And that's exactly what the company does. It says in the Medication Guide this is what -- the things you want to know really about a medicine. What is it, why am I taking it, and what's the worst thing that could happen, right? Those are the things you want to know about a medicine.

And you were never actually shown what the Medication Guide says. You were only ever told about what it doesn't say. What the Medication Guide says that a patient wants to know, what's the most important information I should know about Pradaxa, Pradaxa can cause bleeding, which can be serious and sometimes lead to death.

That's a warning that even their experts acknowledge. It's strong, it's serious, it's truthful. It is a truthful warning. That is a warning that would have been available to Mrs. Knight, to Mrs. Knight's children. There's no allegation, you didn't even hear from Dr. Plunkett that anything in that Medication Guide was untruthful in some way.

The Medication Guide does not say -- and I do want to clarify this because you heard this suggested. The Medication Guide does not say this medicine will be safe for you. In fact, it almost says just the opposite. It provides the most

significant safety information about the medicine that patients need to know.

Now one of the questions that Mr. Childers put to you was why on Earth didn't the company put these other things in the Medication Guide? And I'll tell you why. Because the Medication Guide is intended to be a straightforward, direct communication of the risk of the medicine. So it doesn't have technical information. It doesn't have statistical information. It doesn't have information on every drug interaction that might go along with taking Pradaxa. It gives straightforward risk information that, from a common sense perspective, any patient would recognize is serious.

And it specifically says, you may have a higher risk of bleeding if you have these features. If you're over 75, as Mrs. Knight was. If you have kidney problems, as we know Mrs. Knight did. If you take certain medicines like Plavix or like aspirin. All of those things can increase your risk.

And you know, one way you can figure out whether or not this is normal, whether this is kind of standard is you have access to the Medication Guide for warfarin. You've seen that in the course of this trial. And if you look at the Medication Guide for warfarin, it's very similar. It doesn't talk about how warfarin was studied. It doesn't say you should know that this was a medicine that used to be used as rat poison. It doesn't tell people that.

Warfarin has dozens and dozens and dozens of drug interactions. The warfarin Medication Guide doesn't list every single drug interaction because that is not the way that Medication Guides work. They're intended to give patients, in a brief summary, this is the most important information that you should know.

It also encourages patients to talk with their doctors, and that makes sense because you don't get Pradaxa unless a doctor or another health care professional with the ability to prescribe medicines says to you, this is the right medicine for you.

Roughly 20 times the Medication Guide says to patients, you need to talk to your doctor, starting with saying the Medication Guide does not take the place of talking with your doctor about your medical condition or your treatment. And over and over and over and over again in the Medication Guide it encourages patients to talk with their doctors. Talk with them about what medicines you're using, what your medical history might be. Tell your doctors if you're having symptoms, if you have dark stools, if you have other things that might indicate bleeding.

Then at the very end, it says if you want a copy of the doctor labeling for Pradaxa, talk to your pharmacist, talk to your doctor. They give the website for Pradaxa. And that's available to patients, too.

And that is the other thing I want to talk to you about is the doctor labeling. You've been instructed by the Court that in considering the adequacy of the warnings that BI provided, that you may also consider what the company told doctors, the folks who make decisions about the actual prescription of the medicine.

The doctor labeling has more information in it, there is no question. It has tables and graphs and charts and statistical information. But just like the Med Guide, it's FDA-approved, and it also includes that very same stark, direct, strong warning on why it is you might need to be mindful about prescribing this medicine.

And then throughout that label -- you'll have copies of this in the jury room. 5883, 5884, 5889, those are all versions of the label that you'll have access to. It has all of this information on dosing, on people who might be at higher risk of bleeding, on clinical pharmacology, the clinical trial's experience with the medicine. It's a detailed summary of information about the medicine.

There's the warning on the risk of bleeding with patients who are older.

The other thing that the label does is it tells doctors about changes that might have happened in the contents of the label. And there was a lot of discussion about when people had access to certain labels, and whether they had

certain information at certain times. Based on the testimony of all the experts you heard from, doctors read -- the general practice is to read labels. And in general, based on their testimony, they would expect that it would be reasonable for folks to read the label.

And there's a section in the label that specifically refers to recent major changes, places where you can look in the label where there might have been adjustments in some of the language based on discussions with the FDA.

And one of the things that I want to be very clear about is that, during most of the time that Mrs. Knight was on Pradaxa, every single one of those warnings that you've heard them complain about, those particular items that they complained about on that rolling chart, those were in the labeling for doctors.

This is the instruction that you've been given by the judge, and I want to reiterate it just because of the way the evidence has been presented and the way closing argument was presented. When considering if the warnings provided by BI were adequate, you cannot consider any defect in the patient Medication Guide as a basis for your verdict. And you heard the reason for that. The company is not permitted to change that Medication Guide without FDA's prior approval. So you can't reach a verdict based on determining that the Medication Guide was somehow inadequate.

Now you can consider the physician labeling, that second document that we talked about, in terms of figuring out whether or not the company specifically warned about the issues that are relevant in this case. And if you look at that list, that chart that they rolled out and they rolled back, and they rolled out and they rolled back, every single one of those issues is identified in the doctor labeling for Pradaxa.

The first two items relating to whether or not the 75-milligram dose was tested, patients with severe renal impairment were not studied in RE-LY. That is in section 12 of the label.

Don't take Pradaxa and Coreg. That's that reference to P-gp inhibitors. P-gp inhibitors in patients with severe renal impairment, Pradaxa use not recommended. That is in the label. It's on the very first page, and then it's in the section called Drug Interactions, section 7.

The fact that there was not a reversal agent for Pradaxa, that is specifically called out in the labeling for the product, first in section 10, and then it's repeated again in section 5 at a later in time.

The last item that you've heard so much about, that increased risk of GI bleeding that they saw in Pradaxa patients in the RE-LY study, that is in the Pradaxa doctor label. Every single one of those items is listed.

And importantly, Mrs. Knight was on Pradaxa for 23 months, slightly less than two years. For 22 of those 23 months, every single one of those things was in the labeling for Pradaxa. And there's been no evidence in this case that Dr. MacFarland didn't understand the risks of the medicine, that she didn't read the labeling and understand the concerns.

And there were also prescribers later in time who would have had access to later labeling for the medicine. There is no indication that the folks who took care of Mrs. Knight did anything other than treat her consistent with a full understanding of the risks of taking the medicine Pradaxa.

Now one of the things that they spent a lot of time talking about was the 75-milligram dose. And Dr. Plunkett, in her direct examination testimony, basically suggested to you -- she showed you this document, this company core data sheet. She almost suggested to you that patients with severe renal impairment shouldn't take Pradaxa. You see that language there on the left-hand side.

What you also heard on cross-examination is that when BI submitted an application for Pradaxa in the United States, they told the FDA we didn't test these patients, we wouldn't necessarily ask for a dose for these patients. You know what the FDA did? The FDA struck that language out of the proposed labeling because the FDA made a judgment that it was

appropriate for patients with severe renal impairment to have access to Pradaxa.

And you recall what I went through with Dr. Plunkett in terms of explaining their reasoning on that, that patients with very severe renal impairment are very hard to test in clinical trials. She agreed with that. It's rare that you have severe renally impaired patients in big trials for cardiovascular medicines.

Now does that mean those folks don't get access to the medicine? Of course that's not what that means. It means the FDA comes up with other scientific and medicine based approaches for identifying a dose. And in the case of Pradaxa, what they did was they took the data that they had, and they had the folks at the FDA analyze it and determine -- compare it to folks who had done well in the RE-LY study and tried to figure out what makes sense for a dose for people who have severe renal impairment. That's how they came up with the 75-milligram dose of Pradaxa.

And I want to be very clear about something. When we talk about the FDA, that's not the company hiding behind the FDA. That is not us trying to push off our responsibility. Pradaxa is BI's medicine. We are responsible for it. The company is responsible for the label, every single word of it. But this was the judgment of an outside regulatory agency, the public health agency that we all trust to regulate the

medicines, the prescription medicines that we take.

And it matters, it matters what doctors and professionals and scientists outside of this courtroom have said about that medicine, people who don't have a dog in the hunt who have said we believe this is an appropriate dose for patients who need to take Pradaxa.

And even Dr. Plunkett, after all she said on direct examination, remember what she said? She said I think patients are being treated like guinea pigs. I think this is terrible. I think this is a safety issue.

And I asked her on cross-examination, do you believe that the FDA was wrong when it decided that a 75-milligram dose of Pradaxa should be available for patients with severe renal impairment? You remember what she said? No, I haven't formed that opinion. All of those opinions she offered from the witness stand, she said, no, I don't think they made a mistake.

And then when we talked about it more, I said, isn't it the case when the FDA approves a dose of a medicine, they believe it's safe and it's effective? And she said, yeah, that's what it means when the FDA reaches that conclusion. That was the judgment of the agency.

Now one of the things that's been suggested is that even though the FDA made that decision, the company didn't do enough to test. And you've been told by the Court that there

is not a claim for failing to test the medicine, but I want to show you the evidence on this issue.

The company continued to look at the use of Pradaxa in patients with severe renal impairment. And they were small studies, there's no question about that, and that's because it's hard to study patients with really bad kidneys. The FDA gets every adverse event report submitted to it and evaluates to see if anything is going on. They never raised a concern about the use of the 75-milligram dose. And in fact, they've issued these drug safety communications saying that the FDA continues to believe that Pradaxa provides an important health benefit.

And finally, there are folks outside of the company who have also studied patients in the real world who have used Pradaxa, 75 milligrams, and concluded -- not identified any issues. No one, you've not heard any evidence to suggest that eight years after the medicine was approved, including for patients with severe renal impairment, that somehow there is something going on with that patient population that is just not right. You've never heard that. You've not seen a single piece of evidence on that.

And you've not heard anything to suggest that if there had been more testing, that something different might have been the case for Mrs. Knight. Because ultimately this is a case about her, and every criticism they have, they have to

demonstrate that it would have affected her directly.

One of the things that was interesting when Dr. Plunkett was asked more questions on redirect examination by Mr. Moskow was that he walked her through all of those studies that we talked about on cross-examination. And do you remember what happened, what she did? Every single one, she said not good enough, not enough, not -- not good enough. And you almost got the sense that there was nothing that the company could have done, that the FDA could have done that would have satisfied her.

And what you heard on cross-examination is that that is because this is part of what Dr. Plunkett does for her work. Half of her income is made doing what she did in this courtroom, sitting in a witness box pointing to a company and saying you did something bad. Criticizing labeling approved by the FDA for medicines she is not authorized to prescribe and saying you did something wrong here. Millions of dollars she's made doing just that, traveling to different courtrooms and doing what she did here.

But at the end of the day, I asked her a question because I thought of my granddad who used to say to his grandkids all the time, are you walking what you're talking? That means is what you say consistent with what you're doing in your day-to-day life, right?

And I asked her, now, you said that this is a serious

safety issue. You said this is a really big problem that patients are taking the 75-milligram dose. And she said, yeah, that is what I said.

And I said, Dr. Plunkett, have you ever communicated to the FDA -- you're an FDA consultant. Have you ever communicated to the FDA that you think that's a serious safety issue? Remember what she said? No. Never done anything outside of this courtroom consistent with what she told you about that dose of the medicine. That was a courtroom opinion, not something reflecting what people think in the real world.

The other topic that she addressed, and that counsel addressed on closing, was this issue of blood monitoring, whether patients who were on Pradaxa also need to have their blood measured in some way to be able to use the medicine safely. And I told you at the very beginning the company has looked at that, the FDA has looked at it. It turns out the European regulators have looked at it, too. There's been no recommendation consistent with what you heard in this courtroom.

When the company was doing the RE-LY trial, it collected data from 9,000 or so patients on blood plasma concentration. That wasn't a secret. The FDA knew the company was doing that. All of that data was given to the FDA, and they evaluated it.

One of the things that you heard suggested, not even suggested, it's been said frankly, is that the company had identified a number, a magic number, a magic range, that there is some special place where Pradaxa patients will be monitored and managed safely, right? There's a spot that the company knows about that they haven't told anybody else about. But then when they showed you the documents, they're all different numbers. There's no magic number. There is no magic range. They didn't say to you, aha, we found the smoking gun with this special number that no one has been told about.

Dr. Plunkett testified two days. She came down from the stand. She wrote on a flip chart. She never once, never once wrote on that flip chart this is what the number is. If she knew that, if she had seen that in the company documents, I guarantee you, you would have seen that up on that flip chart, but you didn't.

The evidence is just what the company published. There is no magic number. There is no magic range. There is no single plasma concentration range that provides optimal benefit-risk for patients. That is what you heard.

And you've heard suggestions about marketing, marketing having some role in decision-making. But you know who they played -- whose depositions they played? Medical professionals. Dr. Friedman, who is a nephrologist, a kidney doctor. Ms. Kliewer, who is a nurse by training, who

interacted with the FDA. Dr. Brueckmann, who is a medical doctor. They didn't play -- there was no evidence that they played you or video deposition testimony that they showed you that suggested that marketing folks somehow were the ones who made the decision on this. The folks involved were doctors and scientists and regulatory professionals at the company.

And as the company looked at that issue, they submitted data, they submitted analysis that they did on the RE-LY data. You saw the clinical overview statement where they did that. They submitted the European label that they spent so much time talking about, the company core data sheet that they spent so much time talking about. That's all been given to the FDA. This isn't a hiding exercise by the company. That has all been given to the FDA, and the FDA has made its own evaluation of that data.

This is an example of a chart -- excuse me -- a slide that was shown at a big hearing when they were considering whether Pradaxa should be approved, and they specifically evaluated the relationship between blood levels and what happens in terms of your outcomes. If you have high blood levels, you bleed more. If you have high blood levels, you might also have a reduced risk of stroke. The FDA's scientists and doctors analyzed that on their own.

And after they did that, after they decided to approve the 75-milligram dose, they said we don't think monitoring of

clotting effect is currently recommended. We don't think you need to monitor patients, monitor their blood levels on this medicine. And even Dr. Plunkett confirmed, yeah, that's what FDA decided when it approved the 75-milligram dose of Pradaxa. That was their judgment at the time.

Part of the reason that that's not necessary is because Pradaxa already has a form of monitoring, kidney monitoring. And part of the reason that the company says that in the doctor label is because exposure to Pradaxa increases as your renal function gets worse. That's laid out right there in the labeling in the document.

And you heard exposure increases bleed risk. That's very clear to doctors. There's a table in the label that you'll have access to that shows how your exposure increases if your kidneys are bad.

And what was interesting during Dr. Plunkett's testimony -- because she made this big thing about how there needed to be blood monitoring, right?

And I said, well, Dr. Plunkett, are you saying that people need to be monitored the way that they are monitored on warfarin? And she said, oh, no, that's not what I have in mind. I'm just saying you test their blood levels initially and then check it every once in a while, further assess when necessary based on the patient's characteristics. Turns out that is already what the company tells doctors to do in the

doctor labeling for Pradaxa with regard to kidney function. Kidney function is the thing that determines your blood level exposure.

In dosing adjustments -- it's on the first page of the label, but it is also in section 2.2 -- assess renal function prior to initiation of treatment, just like Dr. Plunkett suggests. Periodically assess renal function as clinically indicated, more frequently in clinical situations that may be associated with a decline in renal function, and adjust therapy accordingly.

Patients on Pradaxa are monitored. Their kidney function, the thing that determines their blood levels and their exposure, that is monitored, and that's what happened with Mrs. Knight. You will see in the records, which we entered yesterday with Dr. Crossley, her kidney function was being repeatedly measured by her doctors, consistently measured. There's not been any suggestion that her doctors were not on close watch for Mrs. Knight when she was on this medicine.

There has also not been any suggestion, any suggestion at all, that that would have made a difference for Mrs. Knight. That if her blood had been monitored, in addition to having her kidneys monitored, that that would have somehow made a difference for her. And that matters because ultimately this is a case about Mrs. Knight and what might

have made a difference for her.

So the question I think I heard was why on Earth don't they tell doctors in the physician labeling that you should also measure blood levels? It is because we already tell doctors you can check renal function, and that's a way to figure out whether people's exposure is going up. That's the answer to that question, because we already warn about the need to monitor kidney function.

And even the doctors you heard from, including the one cardiologist, the only cardiologist you heard from who actually prescribes these medicines, has prescribed these medicines for years and years and years over many decades, he told you, I prescribe Pradaxa, I prescribe Xarelto, I prescribe Eliquis, I prescribe all of these medicines without blood monitoring, and I'm able to treat my patients safely without the need for that. And I don't believe it would have made a difference for Mrs. Knight to have blood monitoring.

That's what Dr. Shami said. Dr. Abdelgaber, he was asked in his deposition, would you have treated her bleed any differently if she had had blood monitoring? And he said no. And the reason for that is because her bleed was managed in the way that bleeds are managed. You stop the Pradaxa, you investigate the source of the bleed, you deal with that once you find the source, and then the patient is discharged. That's what happened.

There is not a single shred of evidence in Mrs. Knight's case that blood monitoring would have made a difference for her, and that is why your answer to that question A, it's the section where all of the claims are listed, should also be no. That should be your answer as to every single one of those claims. Because ultimately all of those claims are about did the company warn enough? Did the company say enough? Did the company make a misrepresentation? And there has been no evidence of a misrepresentation, and there's been ample, abundant evidence of all of the warnings that the company gives to patients and to doctors on the risks with the medicine.

The last topic I want to talk about is the other question that appears on page 2 of the verdict form. That's this question: Did plaintiffs prove that, absent BI's wrongful conduct in any of 1-5 above, Betty Knight would not have taken Pradaxa? And that's really a question about whether or not if that label had been different, if that would have somehow affected whether or not she took Pradaxa. Given everything we know about her history, everything we know about her need for an anticoagulant, everything we know about her time on warfarin, the answer to that is also no.

There's been a lot of discussion in the case about INR levels and Mrs. Knight's specific experience and her INR levels while she was on warfarin. The bottom line is, and I'm

not even sure this is contested, she had wildly variable INR levels.

And even Dr. Ashhab, he told you, they can't keep her -- he looked at this demonstrative, and he said -- Mr. Lewis asked him, they can't keep her within a safe range, right? And he agreed with that. They're having a hard time keeping her in that range of 2 to 3 that protects you slightly more than -- from having a stroke or from having a bleed. They couldn't do that.

Dr. MacFarland said it was dangerous, it was dangerous for her to be too high or for her to be too low. That is a significant thing that has kind of been dismissed, not a big deal, it's just a number on a piece of paper. But for a patient who needs to be protected, who needs to be protected from a potentially catastrophic stroke on the one hand or the possibility of a serious bleed, including a possible brain bleed, those kinds of variations are serious.

And Dr. MacFarland, you know, she talked a lot about how challenging warfarin was for Mrs. Knight, and she talked about how that was part of what led to her decision to transition her from warfarin to Pradaxa. And what I think I heard on closing argument was almost that Dr. MacFarland had written something that wasn't truthful in an insurance form to try to get Pradaxa prescribed. I think that was the suggestion.

Because you saw that form where Dr. MacFarland said the reason I am moving her from warfarin to Pradaxa is because she has been supratherapeutic and sporadic on warfarin. I think Mr. Childers got up and said, well, if she had written the truth, then maybe she wouldn't have been able to get her switched, maybe it wouldn't have been covered. That's a serious claim. That is a serious allegation to make about a doctor who, by every indication, did her very best to try to help Mrs. Knight. That is a serious allegation to make in the absence of any evidence at all and in the face of evidence that Mrs. Knight was having a very hard time on the medicine warfarin.

The other thing that you heard was that Mrs. Knight struggled with warfarin's dietary restrictions. And in some way, this is something where you could say, well, no big deal, just stop eating some things, it's okay. But it can be a burdensome thing. It can be a challenging thing if there are things you really love, and you're dealing with a bunch of other medical issues, and suddenly you're told, well, all of these things you really like you can't eat any more.

And even Mrs. Knight's children told you, she liked greens, and she wasn't supposed to eat them, and we viewed Pradaxa as a chance for her to be able to eat what she wanted to eat. Now that's easy to put down and dismiss, but you heard even from the plaintiffs that that was a real quality of

life issue for Mrs. Knight when she was on warfarin.

And then the last issue was this problem that she had with blood monitoring. This is the record from August of 2008 when she came to the doctor and reported she didn't want to be on coumadin because she just didn't want to do the blood monitoring. And that was not a failing. That was not Mrs. Knight doing something wrong. Lots of patients, you heard this from Dr. Crossley, lots of patients have challenges with that. Mobility issues, transportation issues, some of those were issues that Mrs. Knight had specifically.

And even Dr. MacFarland said it was difficult for her to get her in the office as many times as we needed because of the up and down of the coumadin. Now, if you are well managed on warfarin, maybe you don't have to go in and get checked as much. But when you are up and down and up and down all the time, that means you have to be getting that done more frequently.

Ms. Stevens, Mrs. Knight's daughter, testified she was getting tired of having to go to the doctor a couple of times a week to get the levels checked. That was challenging for her. Those were the circumstances, that's what was going on when there was a decision made to move Mrs. Knight from warfarin to Pradaxa.

And if you look just at the week before that change, she had the same issues that she had had for years and years.

An INR of 8, a 5, a 6.3, a 4.6. That INR on October 10th was so high that when they called it into the doctor's office, the doctor said you gotta get her to the emergency room. This is a serious thing. Those were the circumstances leading to the decision to ask for something that was different.

Now you've heard about a television advertisement. You've not seen the advertisement, you've only had it described to you. But ask yourself -- one of the suggestions that was left was, well, that advertisement was somehow false. It told her she could eat what she wanted to, and she wouldn't need blood monitoring. That wasn't false. She used Pradaxa for two years. It worked for her. She was able to eat what she wanted to, and she didn't need blood monitoring.

To the extent that that was in that advertisement -- and you didn't see it. But if that's what the advertisement said, that's not untruthful. That is exactly what happened with Mrs. Knight, two years of no issues on the medicine other than when she was on triple therapy.

And the doctors you heard from in this case overwhelmingly supported that decision to move her from warfarin to Pradaxa. Now you heard some wordsmithing over whether Dr. Crossley said it would have been appropriate to keep her on warfarin, would that have been okay? And he said, listen, that wouldn't have been below the standard of care if her doctors had done that. I wouldn't have thought it was

unreasonable, but I also think it was a good idea for her to get moved to a NOAC because of all of the things that she had dealt with while she was on warfarin.

There were other folks who took care of her, including Dr. Stephanie Graham, who made that decision at the time that she was on triple therapy that it was appropriate for her to be on Pradaxa, multiple doctors confirming the reasonableness of that decision.

The one doctor who disagreed, the one doctor who told you I don't think that was a good idea was their paid expert, a gastroenterologist who doesn't prescribe Pradaxa, doesn't prescribe it ever because that's not his practice. They didn't bring you a cardiologist who looked at Mrs. Knight's records and said I think that was a bad idea. The only persuasive evidence was that that was a good choice for Mrs. Knight.

Now you have been instructed on this question of proximate cause in terms of the warning. This is the instruction, part of the instruction: If plaintiffs did not prove it is more likely than not that Mrs. Knight read the warnings provided by BI, they cannot prove that different warnings would have caused her to change her behavior.

And that probably makes sense to you. If somebody doesn't read something that has been given to them, then the change in what that was couldn't have affected how that person

made decisions or proceeded.

Now, you may recall when Mr. Knight and Ms. Stevens were testifying, Mr. Childers was asking them questions, at no point during that examination did he ever say to them, did your mom read the Medication Guide for Pradaxa? He never asked that question. There was no evidence of that, he never asked them.

Even as to the two of them, who he said, you know, they were involved in the decision-making, he never asked them, did you all read the Medication Guide? And just to be clear, that is not a criticism of the Knights. I remember during jury selection some people said I read every piece of paper I get when I take a medicine. And some people said, you know, I talk to my doctor, I trust my doctor. Both of those are fine. But for purposes of this claim, they have to demonstrate that Mrs. Knight actually reviewed information.

What you were told during the testimony of Mrs. Knight's children was, well, she kept stuff in a drawer, I know she kept papers from the pharmacy in a drawer at her house. And Lord knows, we've all got papers in a drawer. That's not evidence that that was ever read at any time. That is not evidence of that.

And then what you were told for the first time just yesterday and during closing argument by counsel you were shown this slide -- do you remember this? They showed you

this record from home health, and you were told that this says that Mrs. Knight read her Medication Guide. That's not what that document says, and this is why I would encourage you to actually consider the evidence.

It says patient and caregiver instructed on high risk med Pradaxa for treatment of anticoagulation. Then it says, patient and caregiver verbalized understanding. Now that proved that Mrs. Knight's home health folks had a conversation with her about anticoagulation therapy. That doesn't say that Mrs. Knight ever read a Medication Guide. That doesn't say that, and that's what I mean when I say test the claims against what you actually see in the documents themselves.

Your answer on that last question should be no for a couple of reasons. One is that there's been no evidence that Mrs. Knight ever read the Medication Guide. The other is, if you just consider the evidence as a whole and use your common sense, there is no evidence that if she had read it and it said something different, that would have changed her decision.

This was a patient who had a really hard time on warfarin, someone who had really struggled with that medicine, who was looking -- even by the account of her daughter, Ms. Stevens, who was looking for an alternative medicine. There is no evidence to suggest, no reliable evidence that had that said something different about testing or GI bleeding or

Coreg, there is no evidence that there might have been a different decision made. Because this was a patient who had had a very rocky course on the medicine warfarin, including the variable INRs, GI bleeding that's reflected in her medical records, having to go in and be monitored and finding that challenging for her as she got older. No evidence of that, and so your answer on that question should also be no. Your answer on each one of those questions should be no.

Now I'm coming to the end of my time, and it's tough for me because I don't get to stand up again and talk after Mr. Childers talks one last time. So -- but you all have listened to me talk for a lot of this trial, and you have heard the testimony of our witnesses, so you could probably guess what I would say if he gets back up and says something. And I'd ask you to think, what would she say about that? Let me give you a hint.

I would say, is what you're being told consistent with the evidence? Is it consistent with the actual medical records that were prepared by Mrs. Knight's doctors and nurses and health care professionals at the time, in the real world, before a lawyer or us lawyers ever got involved? Is it consistent? That would be one thing I would ask you, and I'd invite you to ask that question of what you're being told.

The second thing would be is what you're being told being connected to Mrs. Knight? Are they telling you that

what they're describing would have somehow changed her experience on Pradaxa? Which you now know was a two-year course of the medicine where she was protected from strokes. Successful management, she was protected. She didn't have a bleed other than when she was on triple therapy when the medicine worked for her. Are you being told something that shows you that that would have made a difference for Mrs. Knight? Those would be my questions.

I'm going to conclude officially with the following. I mentioned my granddad. He was a plain spoken person, and he was always giving us little nuggets. One thing he used to tell all of his grandkids was, there's no right that doesn't have a responsibility that goes along with it. Every right has a responsibility.

And I've told you we don't quibble with the right of the Knight family to have feelings about the passing of their mother. That is a serious thing. We take that seriously. We tried to treat that with the seriousness that it deserves.

We don't even take issue with their right to bring a claim. That's something we all have the right to do in this country. It's one of the things that makes America a great place to be.

But with that right comes a responsibility to present you with evidence, with more than guesswork, with more than speculation, with more than bullet points that don't match up

with the actual documentary evidence. And I'm going to say this as respectfully but as directly as I can, that has not happened here. They have not discharged their obligation to present you with evidence. And for that reason, your answer on all of those questions on the verdict form should be no, and your verdict should be for BI.

Thank you all for your time, for your attention and for your service as jurors.

THE COURT: All right. The plaintiffs have a few minute for a reply.

MR. CHILDERS: Your Honor, I'm ready whenever you are.

THE COURT: Go ahead.

MR. CHILDERS: Thank you, sir.

I think I honestly just heard that because Betty wanted to eat greens, Ms. Jones thinks she was willing to take a risk by taking a medicine that was too dangerous for her to take. That doesn't make sense. Nobody would do that so they could eat a salad.

She also told you there is no evidence that Betty read the patient Medication Guide. And you saw -- I'm sorry. This is a little hard to read. You saw yesterday, home health care came in, and they went over all of the materials that she had with her. Not only that, we know what materials she kept because Claudia told you. Short of bringing Betty here, which is impossible, that is the evidence to prove that she read the

patient Medication Guide.

I want to go through some of the things that Ms. Jones said to you. I want to start with this slide, no evidence that Mrs. Knight was over-anticoagulated. That's what she said. First of all, Dr. Crossley, Dr. Shami and Dr. Ashhab all told you, she's a patient you expect to have higher levels of Pradaxa. She's over 80, she has severe kidney problems, and she's taking a P-gp inhibitor. That in itself is evidence that she was likely over-anticoagulated. But there is more.

We showed you yesterday, actually we showed you several times through the trial, this is the label in Europe that BI gives to doctors to tell them how to figure out if a patient on the 75-milligram dose might be at an increased risk of bleeding. And I want you to pay attention to this.

The aPTT, it says, times fold upper limit of normal. That means how much more than the top number is it? And it says 1.3. Right? So if it's 1.3 times higher than the high end of the normal range for that test, that patient is probably at an increased bleeding risk.

Well, what did we see here? She had an aPTT of 47. The reference range is -- the high end of the reference range is 37. You multiply that by 1.3, it's 48.1. This test was taken 24 to 36 hours after she had her last dose. It was taken after she had been given two units of blood, which should have brought that number down, and it was still right

at the edge of 1.3 times.

And what Dr. Ashhab told you was he thought she was over-anticoagulated on the 20th. Clearly as this medicine cleared from her system, she had to be over-anticoagulated when she came in with the bleed.

And then they said, well, you heard Dr. Ashhab, he's just guessing. He's not guessing. You have to guesstimate what the Pradaxa level is -- that's the question he was asked -- because they don't tell you how to measure it. They don't tell doctors here how to measure it, so he did the best he could. He used the aPTT test.

And when he did that, along with the fact that he knew she should have a higher level because of all of her issues with renal impairment and her age and her medications, she was likely over-anticoagulated. That has been proven.

I'm going to try to go through these quickly, but that's not it. There is other reasons we've showed Betty had too much Pradaxa in her blood when she bled.

You saw this yesterday and the day before. Betty had an aPTT of 47 when she was on warfarin, and every one of their experts agreed with me, she was over-anticoagulated that day. But when she had a 47 aPTT on Pradaxa, no, we can't say she's over-anticoagulated. That doesn't make sense.

You saw this slide, Pradaxa worked for Mrs. Knight. You know what she didn't show you? So did warfarin. For six

years it worked for her.

She also showed you -- she also showed you this slide, that Mrs. Knight bled after Pradaxa. She didn't show you this slide that said she didn't bleed -- I'm sorry -- with Plavix. She didn't bleed when Plavix was added to coumadin back in 2009.

And then she seemed to complain about the fact that there was -- we disagree on whether there was a GI bleed. And what they rely on -- you saw it -- are three records from a doctor who Dr. Shami told you from the stand, when she swore under oath, yeah, I read his deposition, and he said he never looked at those records. Do you really believe if there was a record that said Mrs. Knight had a GI bleed, they wouldn't have brought it in here with the 4,000 other pages of her medical records? Do you really believe that?

Ms. Jones mentioned that we have to demonstrate to you that Mrs. Knight's injuries would not have occurred other than her being on Pradaxa. Now, keep in mind, our burden is greater weight of the evidence. Is it more likely than not that the injury would not have occurred but for Pradaxa.

We've shown you. She had a 50-percent higher chance of any GI bleed on Pradaxa than warfarin. She had a three times more likely chance to bleed in the lower GI on Pradaxa than warfarin, and that's exactly what happened.

You also saw this, which I thought was interesting,

the Medication Guide. And they said, we gave her the Medication Guide. We told her everything she needs to know. Didn't tell her any of these, not one. I'm bringing the chart back out. They didn't tell her any one of those.

But that's not the only way they communicate with patients. There is something called direct-to-consumer communicating, television ads, magazine ads, newspaper ads, letters to patients. You need to know this information. In this state, their duty is to tell a patient directly, and they did not do that with Ms. Knight.

But let's think about the Medication Guide even further. She showed you, look, we tell patients if you're taking Plavix or aspirin be careful. Where does it say Coreg? Coreg, a medication that is commonly given to AFib patients, it doesn't mention it, not anywhere in the Medication Guide.

You also saw this slide from Ms. Jones where she said, hey, we told the doctors all this information in the label. Not when Betty Knight got the drug. We've been over this. That label when Betty got -- when Betty Knight got the drug, it did not say anything about P-gp inhibitors and severe renal impairment. It didn't say any of that. It didn't say anything in the risk of bleed section about not having an antidote, a reversal agent. It didn't say that.

The label she's talking about is this one. Look at the date, January 2012, after Ms. Knight started Pradaxa. And

there's clear evidence they never sent any communication to doctors to let them know they had made these changes, these changes that would have made a difference to Betty Knight.

I think she showed you this slide about the 75-milligram being studied in real world tests. You know what real world test has never been done? Not one head-to-head test between warfarin and the 75-milligram dose of Pradaxa, not one. They can't tell you there's any proof that the 75-milligram dose is safer, better, anything. They can't tell you how it compares to warfarin.

Then she complained about Dr. Plunkett. She said Dr. Plunkett, well, she just -- she's made millions of dollars from plaintiffs lawyers. Well, she didn't tell you the part that that is over 20 years. In 20 years, she's made over a million dollars working on cases like this.

And then she said, well, she never -- here's the most important one, and she even blew it up -- she's never shared her opinions outside of this courtroom. Okay. You're going to be in the jury room in a few minutes, and you're going to have evidence to look at. I want you to look at every one of the documents that was produced by Boehringer Ingelheim, and you will see at the bottom on every single one of them, it says: Confidential, subject to confidentiality order.

Dr. Plunkett had to sign that to be a witness in this case. She's not allowed to tell her opinions outside this

courtroom. That confidentiality order says the only place you can share this information is in this courtroom, yet they come here and complain that she hasn't somehow told people in violation of the confidentiality order they insist on.

Then they told you her doctors all agree blood monitoring is not necessary for Pradaxa or these doctors do. Well, Dr. Shami, she doesn't even prescribe Pradaxa.

You heard Dr. Crossley. He prescribes it off-label. He's upset with me for -- he thinks I complain about that. Well, here's what he told you. I've got a patient who is on the drug at the dose I'm supposed to give her. She is so over-anticoagulated, her whole body is bruised. Are you telling me it wouldn't be a good idea to monitor her blood level so you know that before she got all bruised up?

And then finally they showed Dr. Abdelgaber, but you heard his own testimony. They never told him that it mattered, that you could even be over-anticoagulated, you could have too much Pradaxa in your blood. He didn't know that when I said that to him. Why would he think he needs to measure if he doesn't know that a patient could have too much in their system?

I showed you this slide, and you've seen this a few times. And if you recall, we saw that slide with Dr. Shami. And what Dr. Shami said was, well, when I looked at these, I counted them all up, and 40 percent of the time it was too --

it was right, excuse me, and 60 percent of the time it was too high. But when I asked her about the fact that she hadn't actually calculated it right, what did she say? Yeah, that's true, I didn't.

And when I asked her if you calculate it, you'd agree with me it's about 60 percent? She said, yeah, I think that's probably right. I wouldn't be surprised.

And then she agreed with us 60 percent in range, therapeutic time and range is higher than the warfarin patients they tested Pradaxa against in the RE-LY trial. But they want to come in and say her time and therapeutic range was just awful. That is a misrepresentation. But it's not the only misrepresentation.

You remember this. They wanted to come in here, and they wanted to say her aPTTs were high all over the place. Unfortunately, they were telling you something that wasn't true. Those tests weren't aPTT tests. But for us calling them on it, it probably would have been in their closing argument slides.

And this one, I like this one a lot, Pradaxa was appropriate for Mrs. Knight, and you see all these doctors against Dr. Ashhab. Well, you know what else doesn't agree with this? The January 2012 Pradaxa label says this drug was not appropriate for Ms. Knight. But they didn't share that information with her, and they never told her doctors through

a dear doctor letter or any other communication that they had made that change. So it's not just Dr. Ashhab who says it, it's the company who says this was not the right medicine for her.

Throughout this trial and throughout the closing argument, it's been one thing, they will not accept any responsibility. It's clear they didn't warn patients about these risks. And when you do something wrong, you take responsibility. And if you don't take responsibility, we come to a court of law, and a jury like you holds them responsible.

What have they done instead? Blame game. Betty Knight, throwing fault, she wanted to eat salads. She might have been bleeding before she got to the doctor; she should have come sooner.

Or no, no, no. You know what, actually it's the doctor's fault, even this mystery Dr. Graham, who they didn't even have a picture of. Did you notice that? It was just like a silhouette of somebody. They should have known better.

And then it's the FDA made us sell this dose of the drug. Great. If FDA wants you to sell it, no problem. Just tell patients what you know about it. And what you know about it is we don't know anything about it. Tell them that.

It's time for you to make Boehringer accept responsibility. They didn't warn. They told Betty and her family things that were not true about the drug. Pradaxa was

a cause of her bleed, and that bleed debilitated her to such an extent that she could not sustain the heart attack that she suffered.

When you go back in the jury room, look at the evidence. I don't run away from any evidence. Look at all of it, look at any of it, and I think you'll come to the same conclusion. And all we ask is that you do what's right and you do what's fair, and in my heart I believe that that is a finding for the plaintiffs.

Thank you.

THE COURT: All right. Ladies and Gentlemen, when you retire to the jury room, you should first select one of your number to act as the foreperson of the jury. The foreperson will preside over your deliberations and be your spokesperson here in court.

All jurors must agree on a verdict. Your verdict must be unanimous.

You must consult with one another and deliberate with the intention of reaching a verdict if you can do so without violence to your individual judgments. During your deliberations, do not hesitate to reexamine your own views or to change your opinion. But do not surrender your views or opinions just to reach a verdict.

I have prepared a verdict form for you. The lawyers have shown it to you in their closings. When you have reached

a unanimous verdict, your foreperson should fill it in, date it and sign it, and then let the court security officer know that you have reached a unanimous verdict.

You will receive, as the lawyers have explained, a box of exhibits that have been introduced. Along with that, you will receive the list of those exhibits that my deputy clerk has maintained throughout the trial. You can use that list to identify and locate any of the exhibits that you want to look at more carefully.

Second, I'm going to give you a copy of the instructions that I read to you. I want to emphasize that when you're looking at these instructions, you should consider them as a whole. Apply your common sense, common understanding to the terms in there and consider the instructions as a whole as you deliberate on reaching a verdict.

If at any point you want to take a break or recess for the day, just send me a note through the court security officer.

If you have any other matter, question or anything else, also I would request that you reduce it to writing, a simple note. Give it to the court security officer, and he'll bring it to me, and I'll deal with the parties if it's a matter that involves them as well.

Obviously you've been here a long time already this

morning. One of the first things you probably should do when you first go back to deliberate is decide whether you want to go take a lunch break now or start deliberating. At this point, the schedule is in your control.

So I'm going to allow you to retire to the jury room to begin your deliberations. If you decide now or in a while that you want to take a break for lunch or otherwise, just let us know, and I do have to instruct you as I have in the past about matters when you actually leave deliberation. But it will be up to you.

With that, you may retire to the jury room. It will take a couple of minutes for us to bring the box of exhibits, the instructions and anything else to you.

(Jury not present.)

THE COURT: I have one matter I want to take up with counsel.

MR. LEWIS: We have something, too, Your Honor, when --

THE COURT: Go ahead.

MR. LEWIS: Based on the rebuttal that Mr. Childers did, he raised an issue that the jury heard for the first time, which is the designation on the bottom of some of the documents that the documents are marked confidential pursuant to a protective order. And that is an order that was entered by the Court to govern the exchange of documents in

litigation.

He clearly misled the jury into thinking that Boehringer alone came up with that and is preventing Dr. Plunkett from revealing information, and that was terribly misleading. We didn't object to it because it was closing argument, and you don't object in the middle of a five-minute presentation, but I think the jury needs to be instructed about that issue.

MR. CHILDERS: Judge, the argument on closing by the defense was their main criticism of Dr. Plunkett is she hasn't shared her opinions --

THE COURT: Hold on.

What did they want?

(Pause in proceedings.)

THE COURT SECURITY OFFICER: They want to take a lunch.

THE COURT: Bring them out. We'll let the jury go, make this easy. Tell them we're going to take a lunch break.

(Jury present.)

THE COURT: All right. The jurors want to take a lunch break.

Apparently you said like 35 minutes; is that --

JUROR NO. 17: 30 to 45.

THE COURT: All right. How about we come back at 2:15. Is that long enough?

All right. Remember my instructions. Don't discuss the case or allow anyone to discuss it with you. You should not have any discussions among yourselves or with each other about the case or the evidence or what a verdict might be.

With that, we'll see you back here at 2:15.

When you all get back together, when all nine of you are present, you may resume your deliberations.

(Jury not present.)

THE COURT: You may be seated.

All right. Mr. Lewis, what relief are you requesting?

MR. LEWIS: I'm requesting an instruction be given to the jury on the nature of the confidentiality order, the fact that it was entered by the Court, that it's appropriate.

And also that documents that are put into the trial no longer maintain their confidentiality. She's testified in three trials. I mean, he completely misled the jury into thinking that she's not permitted to tell anyone about what her scientific views are based on the confidentiality provisions at the bottom of some of those documents. I think it's completely misleading, and they need to be -- it needs to be explained to them that that's not the case.

THE COURT: All right. Mr. Childers, you want to respond to that?

MR. CHILDERS: Yes, Your Honor.

The argument that was made was the main criticism of

Dr. Plunkett was she hasn't shared her opinions about Pradaxa that she bases largely on the documents that she read that came from Boehringer, that bear a confidentiality stamp, outside of the courtroom. And I believe Ms. Jones even said my grandfather taught me to walk the walk or something along that line, and she hasn't walked the walk. She made a huge point of the fact that these opinions haven't been shared out of the courtroom when the very reason for that is the confidentiality that she had to sign. I didn't insist on a confidentiality order, that was their insistence.

THE COURT: Well --

MR. LEWIS: The problem is, Your Honor, the testimony in the case was from Dr. Plunkett, and that's what she said in response to the question. If he wanted to have a redirect with Dr. Plunkett and go through why she hasn't explained something to the FDA, that should have been evidence in the case, and it wasn't. So what Mr. Childers did is to comment on something that is not evidence, mislead the jury with information that now they're going to consider in their deliberations. It needs to be corrected.

THE COURT: Well, I agree with the defendant. The witness testified about her work. She was asked on cross about whether she did any work for or with the FDA or whether she had made -- I don't recall what the phrasing was but, in essence, whether or not she had been involved in any matter

where she publicly shared her opinions, and she said she had not.

I believe you went beyond just referencing what was restricted under the confidentiality order. The defendant's right about that. While the use of the documents bear a restriction, her testimony at trial does not, and you really didn't limit your discussion of these restrictions to just that she can't go out and offer opinions publicly about confidential documents.

Having said -- go ahead.

MR. CHILDERS: Your Honor, the order she has to sign and that we have to sign says we can't use the documents or the information we get from them outside of this litigation. That's what it says. And she signed it just like we did. So to somehow say, well, she should be able to go out and say things because she'd testified in trial, she's not a lawyer. She signed a confidentiality order. For all she knows, if she goes and does that, they're going to file a lawsuit against her and say she breached the confidentiality.

Not one of those documents has had the confidentiality stamp taken off. It's still there. She's doing her job, which is follow the rules.

MR. LEWIS: But, Your Honor, the problem is twofold. One, the protective order has an exception for trial and testimony. Number two, that's not evidence in the case.

If they wanted to have Dr. Plunkett explain why she hasn't talked to anybody else, then that should have been evidence. He's commenting on things to the jury that never came in in a misleading way. That is inappropriate in closing.

MS. JONES: And, Your Honor, if I could just add one other thing.

I specifically referenced the fact that Dr. Plunkett had testified that she never conveyed to the FDA that she believed that the 75-milligram dose presents some kind of public health safety issue. Her opinions on that issue are based, I assume, on the FDA's publicly available memoranda and documentation relating to its decision. My comments in that regard were related to that specifically -- that specific Q and A, and she is not precluded by any confidentiality order from saying to the FDA, based on what is publicly known about what it did with the 75, that she thinks that was a bad idea or a mistake by the FDA.

So the closing argument that I made was specifically focused on her testimony on the 75. All of that information is based on FDA memos that she reviewed, which she can comment on freely. We're not able to bind the subject matter of the FDA's deliberations.

MR. CHILDERS: Judge, may I show you the slide? Because I think it's very important.

THE COURT: Yes.

MR. CHILDERS: The slide says, never shared her opinions outside of the courtroom. She signed a confidentiality order saying I won't do that. I won't share these opinions -- I won't share this information, excuse me, that I have gathered from any of these documents outside of this litigation.

If this had said what Ms. Jones just said it says, maybe we have a different issue. But this clearly says they are complaining that she hasn't gone out and talked about the stuff that she had to sign a confidentiality order about not talking about outside of the litigation.

MS. JONES: This slide was right after a slide about the 75-milligram. This was all in the context of talking about the 75-milligram and publicly available articles that were on the study of the 75-milligram outside of the approval process. That is what I was talking about. That's the specific question and answer that I referenced.

What he said went well beyond what she would have been limited to doing and did leave a misimpression about what she was permitted to do or not to do. If she wanted to, there is no question that she could communicate with FDA about her view that the 75-milligram dose presented some kind of public health hazard. There's no question about that. And her basis for that view is the FDA materials, which are not subject to a

confidentiality order. There's no question about that.

THE COURT: Well, tell me succinctly what it is you would ask the Court to instruct to the jury.

MR. LEWIS: We probably need to craft some kind of an instruction to the jury to explain what that reference was and to undo the misleading and mischaracterization of a protective order, among other things.

MS. JONES: I would think the priority issue would be, to the extent that there's a confidentiality order, that is an order that the Court has entered. That's not something, as he suggested, that the company has somehow forced on them. That's an order of the Court that he's criticizing when he talks about that little stamp at the bottom.

And I do think there should be some clarification with regard to what he said in connection with what I specifically said in my closing argument, which was related to the 75-milligram dose.

MR. CHILDERS: Your Honor, what I said was that they insisted on the confidentiality order. That is absolutely true. They wouldn't give us documents until there was one entered by the Court. That's not a mischaracterization. To say that a confidentiality order means you can't share information outside of court, that's not a mischaracterization, that's not a misrepresentation. That is what it is.

So I understand you want to maybe say something to the jury, but I don't believe anything was misrepresented as to the nature of the confidentiality order or the fact that she had to sign one in order to look at the documents that they produced. That is just the truth, and it was something that was insisted upon by the defendant, and they didn't produce any documents until it was entered.

THE COURT: I will consider some succinct brief statement. You can prepare it, give it to me, provide it to the plaintiffs before the jury comes back from lunch.

MR. LEWIS: Okay. Thank you, Your Honor.

THE COURT: Anything else?

MR. CHILDERS: No, Your Honor. Thank you.

THE COURT: All right. We stand in recess until 2:15.

THE COURT SECURITY OFFICER: All rise. This honorable court is in recess.

(Lunch recess taken at 1:45 p.m.)

(2:17 p.m. in open court, jury not present.)

THE COURT: Briefly, do you want to just state it? He's getting my copy.

MR. LEWIS: We propose, Your Honor, the following instruction be read to the jury:

You heard a reference by plaintiffs' counsel in his rebuttal argument to the confidentiality order. The confidentiality order was entered by the Court, not by either of the parties.

Plaintiffs' expert, Dr. Plunkett, relied on both documents that were subject to the confidentiality order and documents that were publicly available. Nothing in the confidentiality order precluded Dr. Plunkett from sharing the opinions she has expressed for the FDA.

THE COURT: All right.

MR. CHILDERS: A few issues, Judge.

One, although the protective order was entered by the Court, the parties signed it and a motion was filed to approve it. It wasn't the Court's own initiative.

Second, the last sentence of that, that nothing precluded her from sharing that information with the Court, is completely erroneous. She's -- we're saying she relied on internal documents and external documents to form an opinion. She's not allowed to then go tell the FDA something that she gleaned from an internal document that's

confidential. That's just not -- that's not true.

THE COURT: All right. I think there's a much simpler way for the Court to handle it that would be both proper and sufficient.

I intend to instruct the jury simply that in his closing reply arguments Mr. Childers made reference to Dr. Plunkett's testimony and he referred to the fact that there are documents that are marked confidential.

The Court observes that Dr. Plunkett did not testify that any confidentiality or other protective order restricted her review. So the counsel's statement should be disregarded.

I do not intend to get into a deeper discussion of the effect of the protective order. That wasn't a matter of evidence. And the Court believes that to introduce the subject the way the defendant has suggested would result in considerable confusion and possibly misstate the effect of the order. So both sides can object to what my plan is.

MR. CHILDERS: That's fine, Your Honor. We just want to get them going.

MR. LEWIS: I think, I think what the Court proposed is reasonable. I would -- my only suggestion is when talking about the restriction, I think it needs to be focused on what he argued which is restricted her use, no communication.

THE COURT: Well, I --

MR. LEWIS: That's the way it was used. And, Your Honor, I mean, I'm not trying to quibble here but this -- what, what was done in rebuttal was a serious violation. It was a comment on something that's not in evidence on an issue about keeping the public from getting certain information.

And this is a -- the claims in this case are significant and they include punitive damages. And, so, this needs to be corrected because the jury could certainly draw the conclusion based on no evidence whatsoever that Boehringer is attempting to restrict an FDA consultant from telling the world about a problem she knows about. That's a false and misleading statement.

THE COURT: All right. Thank you. Let's bring the jury in.

(Jury returned into the courtroom at 2:23 p.m.)

THE COURT: This won't take long. Come on in.

All right. It came to my attention that in his rebuttal reply argument for plaintiffs, Mr. Childers made a reference to Dr. Plunkett, the plaintiffs' expert, and made mention of the fact that some of the documents that are in evidence and that she may have reviewed had a line at the bottom that referred to confidentiality and how that might have restricted her use of that document or similar

documents outside of this court.

Dr. Plunkett did not offer any testimony about any restriction on her use of information based upon confidentiality notes or protective orders or such things.

Since there's no evidence from Dr. Plunkett about that, I instruct you to disregard Mr. Childers' brief statements in reference to that that he made at the end of his rebuttal argument.

With that, go deliberate.

Terry is going to come in and explain one sort of technical matter about the exhibits just so you'll understand how they're boxed.

I have yet another matter to take up with the parties.

(Jury retired to the jury room at 2:25 p.m.)

THE COURT: Be seated.

Since we have no idea how long the jury will deliberate or what the verdict will be, obviously, I wanted to, while we're still fresh, relatively speaking, address the possibility that the jury might come back with a plaintiffs' verdict and an answer to the punitive damage question that finds against the defendant.

It seems to me that there's a range of activities that could follow. And, so, I want to discuss it now because I want to be able for us to quickly pivot to that if we need to to keep this jury moving.

So at a minimum it seems to me the appropriate step to take if the verdict comes back that way is to first instruct the jury in accordance with the pattern instruction concerning how they should evaluate, measure, and determine punitive damages.

And, secondly, then to have counsel have a brief period to make closing arguments on punitive damages and then submit that case to the -- that issue to the jury for determination.

Do the parties agree to that or do you think there's some other procedure or process we should follow?

MR. CHILDERS: I apologize, Your Honor. I may have missed it. Did you say there would be a period of putting in evidence about --

THE COURT: Well, I guess -- I didn't say that and that's sort of my question to you.

MR. CHILDERS: So my understanding and how I've done in the past is we actually have to present some evidence of the defendant's net worth in order for the jury to properly evaluate punitives.

And I know Your Honor had also reserved ruling on whether or not we could show the launch video if we got to that point. And plaintiffs would again ask that we be allowed to show the jury that video as part of punitive damages.

THE COURT: And do you have specific evidence that you would offer as to the worth of the company?

MR. CHILDERS: My hope would be that we could just stipulate to that. They're not a public company, so they don't have a 10-K or a 10-Q or any of that. In the past that's how I've done it. But it's a closely held company.

We have some testimony from Dr. Barner which we could play along with during the launch video where he talks about profit and the gross revenues of the company.

THE COURT: Is that part of the launch video?

MR. CHILDERS: It's not -- the deposition -- he talks about the launch video and then he also talks about the company's worth.

THE COURT: Okay.

MR. CHILDERS: So we could do that.

THE COURT: All right. About how long is the, is the deposition video talking about the company's worth?

MR. CHILDERS: Probably less than five minutes, Judge. It's in German. It's translated. I don't know if it's synced is what Gina calls it. And then the launch video is about five minutes.

THE COURT: Okay. What's the defendant say?

MR. LEWIS: We have an objection to the launch video. I think Your Honor is aware of that.

I'd like to consider the possibility of some sort of

stipulation. I mean, I've never had a bifurcated proceeding where it went that way, but I've heard that's how it typically is done. So maybe we can discuss that during this time frame.

THE COURT: Well, certainly. I then will direct that the parties confer about the possibility of a stipulation as to relevant facts pertaining to the financial status of the company.

If, if that's not reached, I would at least, I'm certain, allow them to play the deposition. And we'll have a chance again to talk about the launch video before I decide that.

But under those circumstances, what evidence, if any, would you expect to adduce?

MR. LEWIS: I think we would probably just rely on argument about the evidence that's already been put in.

THE COURT: All right. So why don't you folks talk about a stipulation and see if that can be reached. I'll be thinking about this launch video. But I'd like to be ready to proceed pretty quickly. You all know as well as I do how hard this jury has worked.

And if they want to work through the afternoon and evening to reach a verdict, which would not surprise me, you never know, I'd like to be prepared to tell them as soon as the initial verdict comes back of the necessity of

continuing. And then it will be up to them to decide, depending on the hour, whether we'll do this today or come back tomorrow to finish that portion. All right?

MR. CHILDERS: Thank you, Judge.

THE COURT: All right. We'll stand in recess.

(Recess taken at 2:30 p.m.)

(Back on the record at 3:41 p.m.)

(Jury not present.)

THE COURT: All right. My law clerk just showed you the note we got from the jury, but I'll put it on the record.

It reads: On page 8 of the jury instructions, it says that the "Plaintiffs must prove all of the following," then goes on to list four items. Must we agree on all four or three of the four, et cetera?

So I've looked at the instructions. I think with respect to this claim and the other claims, there are a number of elements with respect to each, and the instruction properly tells the jury they have to find all four or whatever that number is. So I intend to bring them out and essentially state with respect to their particular question, as well as the other claims with similar numbered elements, they must agree upon each and all of the elements.

Okay? Anybody object or --

MR. CHILDERS: Just not looking at them, I wasn't sure if there were any that said "or," but I know this one does not, Your Honor, that they asked about.

THE COURT: I think they're all stated properly as essential elements with "and."

MR. CHILDERS: Yes, sir. I meant if there's any other instruction with numbers, if there might be one that's not an "and." And I don't know the answer to that.

THE COURT: And I think with respect to the claims, they're all "and," and they are all listed that way.

MR. CHILDERS: Understood, Your Honor.

MR. LEWIS: Your Honor, may I?

So if the jury found unanimously that one of the elements was not met, I believe it would be appropriate to find that the claim was not met.

THE COURT: Well, that is true, and they don't even all have to agree to that. If any juror does not believe that any one of the four elements has been proven by a greater weight of the evidence, they do not have a unanimous verdict on that element.

MR. LEWIS: Right.

I guess my -- the question from the jury is a little bit confusing. What I'm --

THE COURT: I'll read it again: Must we agree to all four or three of the four, et cetera?

What I take that to mean is that they're asking whether the jury must unanimously agree that plaintiffs have proven each of the four elements.

MR. LEWIS: Correct.

THE COURT: And the answer to that is yes.

MR. LEWIS: Right. And I guess my point is, they could also be asking what if we agree that the plaintiffs haven't proven one of the four elements, but we can't agree on

the others.

MR. CHILDERS: Your Honor, they didn't ask that. I think the question asked has to be answered as they asked it.

MR. LEWIS: Okay.

THE COURT: Yeah, they only asked about what if they agree.

All right. Let's bring the jury out.

(Jury present.)

THE COURT: All right. You may be seated.

So let me read the note that you've given me. It reads: On page 8 of the jury instructions, it says that the "Plaintiffs must prove all of the following," then goes on to list four items. Must we agree to all four or three of the four, et cetera?

So I refer you to the instructions. First, you're referring specifically to page 8, and you're referring to the instruction on the claim that is characterized or summarized as strict liability failure to warn.

And as the instruction states, to establish that claim, the plaintiff must prove all of the following. That means the plaintiff must prove by a greater weight of the evidence each and all of the four items listed there in order for you to find for the plaintiff on that particular claim.

You'll see that, as you go through the balance of the claims, the other claims similarly have a numbered listing.

Those are considered elements of the claim which the plaintiff must prove to your satisfaction with respect to each of those other claims as well.

With that, you may retire to the jury room and resume your deliberations.

We will file and make as part of the record the question.

(Jury not present.)

THE COURT: Anything else?

MR. CHILDERS: No, Judge.

MR. MOSKOW: Thank you, Your Honor.

MR. CHILDERS: Thank you, Your Honor.

(Off the record at 3:47 p.m.)

(Back on the record at 5:20 p.m.)

(Jury not present.)

THE COURT: All right. We're advised that the jury has reached a verdict.

Let's bring the jury out.

THE COURT SECURITY OFFICER: Yes, Your Honor.

THE COURT: As the jury is coming out, obviously I don't know what their verdict is, but I commend counsel for both sides. This was an extremely challenging, difficult case. I can't imagine how both sides have been able to master so much about this case from all these different angles, and I respect the level of performance that I've seen in this trial.

MR. CHILDERS: Thank you, Judge.

MR. MOSKOW: Thank you, Your Honor.

MR. LEWIS: Thank you, Your Honor.

(Jury present.)

THE COURT: All right. I am advised the jury has reached a verdict. Who has the verdict form?

Would you please pass it to my court security officer, and he will bring it up to me so I can inspect it.

Before I see your verdict, I want to thank all of you publicly. I know that the parties join me as well. We know this has been a difficult case, a very lengthy case, a huge amount of material, many witnesses, many complicated matters. We appreciate and respect your service.

I don't know if any of you had actually served on a jury before. I don't recall that any of you have. As is often the case, though, I think you'll find that now having done it you will realize how important it is for our system of civil justice to have citizens who are imposed upon, but as a result of their civic duty serve as jurors in cases like this to help us resolve these matters. I think it makes it the best system. We know it's been a sacrifice for you folks. Regardless of your decision, we all thank you for your work.

All right. I'm now going to pass the verdict form up to my clerk. I'm going to ask that she read it aloud. Make sure each of you listen to it, and that it is your verdict,

each of you, in all respects.

THE CLERK: We, the jury in the above-captioned matter, unanimously answer the following questions:

I. Liability.

A. Plaintiffs' claims: As to each of plaintiffs' claims, mark "YES" if plaintiffs have proven the elements of the claim as the Court instructed or "NO" if you find the elements of the claim have not been proven.

1. Strict liability failure to warn: No.

2. Negligent failure to warn: No.

3. Breach of express warranty: No.

4. Breach of implied warranty: No.

5. Fraud: Yes.

B. Legal Causation: Did plaintiffs prove that, absent BI's wrongful conduct in any of 1-5 above, Betty Knight would not have taken Pradaxa? Yes.

7. Did plaintiffs prove that Pradaxa proximately caused Betty Knight's injuries? Yes.

8. Did plaintiffs prove that Pradaxa proximately caused Betty Knight's death? No.

II. Damages.

What amount of money would fairly and reasonably compensate plaintiffs for Betty Knight's injuries?

Economic damages: $50,000.

Non-economic damages: $200,000.

What amount of money would fairly and reasonably compensate plaintiffs for Betty Knight's death?

Wrongful death: N/A.

Did plaintiffs prove by clear and convincing evidence that BI acted with actual malice toward Betty Knight, or that BI acted with a conscious, reckless, and outrageous indifference to the health, safety and welfare of others? Yes.

THE COURT: All right, Ladies and Gentlemen.

Do the parties want the jury polled?

MR. CHILDERS: No, Judge.

MS. JONES: Yes, Your Honor. Thank you.

THE COURT: All right.

THE CLERK: Ladies and Gentlemen, if this is your verdict, please answer Yes. If it is not, please answer No.

Anita Kay.

JUROR NO. 2: Yes.

THE CLERK: Michael Cochran.

JUROR NO. 6: Yes.

THE CLERK: Paul Koza.

JUROR NO. 22: Yes.

THE CLERK: Tommy White.

JUROR NO. 23: Yes.

THE CLERK: Colby Sayre.

JUROR NO. 26: Yes.

THE CLERK: Eric Crum.

JUROR NO. 8: Yes.

THE CLERK: Sean Loring.

JUROR NO. 11: Yes.

THE CLERK: Michelle James.

JUROR NO. 17: Yes.

THE CLERK: Carlos Mann.

JUROR NO. 15: Yes.

THE COURT: All right. Ladies and Gentlemen, I will accept your verdict. I will order that it be filed and made a part of the record.

I'm now going to ask you to retire back to the jury room. There will be one other matter that the Court will need to address with you. With that, you'll retire to the jury room. We'll be back with you shortly.

(Jury not present.)

THE COURT: All right. As you just heard, the jury has returned its verdict. It has found the defendant liable under the fraud count and awarded compensatory damages and has also found that the defendant is subject to punitive damages. We addressed this briefly earlier.

Have the parties prepared a stipulation or entered into any stipulation?

MR. MOSKOW: No, Your Honor. Plaintiff provided a brief play of Dr. Barner about an hour and a half ago or so

and invited a stipulation, but we haven't received one.

MR. LEWIS: I think we'll just stick with the play that they're going to -- the video play. And then on our side, we have a few documents, as we have thought about the issue, that we would like to move into admission and discuss in a mini argument if we can.

THE COURT: Have you identified the documents or --

MR. LEWIS: We have not yet. We were just going over those during the break, so I need to confer. The documents are on our exhibit list, though.

MR. CHILDERS: May we at least know what they are?

My understanding with the Phase II part of the trial is just economic issues, that the behavior issues have already been established.

MR. LEWIS: Well, I'm not -- so when I read the instruction, Your Honor, there were I think five elements that the jury may take into account, and it's not just financial. There's a reprehensibility aspect to it. And so the evidence that we are seeking to admit would be post conduct, conduct after the events that took place to show that we've made corrections and addressed some of the things that were at issue in the case.

MR. MOSKOW: Your Honor, without knowing what the documents are, it's hard to argue in a vacuum. But as the Court is well aware, we weren't able to put in evidence

regarding the development of the reversal agent, which we believe, you know, would have demonstrated actual knowledge at the time that this drug had dangerous propensities and might have allowed the jury to find on other counts. And so now to allow post conduct evidence to somehow show that they have mitigated their conduct seems to me unfair given the way the case was presented to the jury.

MR. LEWIS: Well, I think it's -- that would be -- that was one of the topics that we would seek to address is the fact that plaintiffs argued and there was no evidence in this case that we had a reversal agent for this particular medicine, and we have since gotten approval and have a reversal agent, as an example, for this particular medicine.

I think when the jury is considering punishment, punitive damages, it ought to consider what the company has done to address the alleged deficiencies in the underlying case.

THE COURT: Well -- go ahead. You can respond to that.

MR. CHILDERS: Your Honor, if you'll recall, the issue of the reversal agent was kept out of the case based on summary judgment filed by the defendant. If now they want to put in evidence that they now have a reversal agent, without us being able to demonstrate what we wanted to show the jury, which was they knew how to do it well before the drug came on

the market, I don't believe that is fair, and I don't think that is part of how the punitive side of this works.

Maybe I'm wrong. It's not that often I have gotten to a punitive phase. But when I have, I haven't seen evidence like that come in, Your Honor. And I'm happy to do some research, whatever it may be.

But my understanding, especially after what you told us earlier, was get your stuff together. And what we heard from defendant was we're just going to argue, we're not going to put on any evidence.

MR. LEWIS: Well, we were making a decision in real time and had just been proffered the question. We've thought about it during the break.

I was trying to pull the instruction, Your Honor, as to things that the jury is to consider.

MR. CHILDERS: Your Honor, in that case, if we play the launch video, they can put in whatever they want.

MR. LEWIS: Well, the launch video we've already discussed, and the Court has ruled that that is not admissible. And we would argue that that is not admissible in this phase of the case either because it's not directed at relevant conduct that's at issue.

For instance, the concept of a reversal agent and the fact that we've later developed a reversal agent is to show the jury not that we have -- we shouldn't have been found

liable, but that we're taking corrective measures. That's what punitive damages are for. Punitive damages are for don't do this again or teach them a lesson or have you learned your lesson. And we ought to be able to tell the jury about conduct subsequent that suggests that we've taken an action and invested in that.

THE COURT: All right. I'm going to take a brief recess. I will look into this a little more before I decide the scope of evidence that could be presented in addition to argument.

We stand in a brief recess.

MR. LEWIS: Thank you.

MR. CHILDERS: Thank you, Your Honor.

THE COURT SECURITY OFFICER: All rise. This honorable court will be in recess.

(Recess taken from 5:30 to 5:38 p.m.)

THE COURT: All right. So as I'm working through this, I wanted to bring your attention to West Virginia statutory law, which I think applies.

MR. CHILDERS: Yes, sir.

THE COURT: 55-7-29, have you all looked at this section?

MR. CHILDERS: Yes, sir.

THE COURT: Have you?

MR. LEWIS: Yes.

THE COURT: So for one thing, it limits the amount of punitive damages. I don't know that it provides any other direction or guidance to the Court when we're in this situation, although it does either require or suggest bifurcation, which we've already undertaken.

So do counsel have any further suggestion based on the statute?

MR. CHILDERS: The only thing I would point out, Your Honor, my understanding and how I've seen it done as well in states that have caps on punitives, the jury may award whatever number they want. Obviously the Court would then reduce it to the amount of the cap. So we would just request that we don't be restricted to only asking for the cap amount.

MR. LEWIS: I guess our question on our end is kind of are we just telling the jury what the financial information is, and then they go back and deliberate? Or are we making arguments about the conduct?

THE COURT: Well --

MR. LEWIS: Because that's what I'm trying -- that's what we're not sure of on our end.

THE COURT: That's to me really the important question, and the statute doesn't provide us any guidance there as I read it.

The Court notes, as the parties have, that the pattern instruction addresses the elements of a punitive damage award,

requiring that it bear a reasonable relationship to the harm likely to occur from the conduct and that has actually occurred; and then to take into account how long the defendant continued its actions; whether it was aware that its actions were causing or likely to cause harm; whether it attempted to conceal or cover up its actions or harm; and how often it engaged in similar conduct.

And then last, the extent to which the company profited from wrongful conduct so the jury could consider an award that would discourage future bad acts.

Based upon that, I think I have to make an opportunity available to both parties, but in this instance it is really to the defendant who has raised this, an opportunity to present evidence about its post wrongful conduct actions here.

MR. LEWIS: And I guess our question is, if the Court was just inclined to provide the financial information to the jury without getting into the argument about because of this conduct you should really, you know, do this, that and the other thing, if it was just financial information that the jury got and then went back and deliberated that, then we wouldn't put in all of this evidence.

But if there is going to be an argument continuing about how they have to punish us based on kind of we haven't learned our lesson yet, then I'm torn because then I feel like they need to know more. But I guess we just need to

understand how the proceeding would go before we take a position on what we want to do.

THE COURT: Sure.

MR. CHILDERS: And, Your Honor, I would envision an argument being the statute says you have to award an amount to punish and deter. They've already decided they need to be punished. And then it goes into the amount of money that would be required to do that, not they've done this or that. We've already shown them what they did, and so I don't think we need to go beyond this is how much money they have for us to make those arguments.

THE COURT: Well, so it sounds like the plaintiffs are satisfied if they get to produce evidence, either through stipulation or through the deposition testimony, by which you've developed evidence about the company's financial worth or something to that effect, you're willing to leave it at that is what I'm hearing.

MR. CHILDERS: That's correct, Your Honor.

The video we have goes through with the former CEO the amount of money they made in year unfortunately 2016, because that was the most recent year, how much that was, how much of that was profit, and how many people are shareholders, that kind of thing, so they can understand who they are punishing and how they would have to do it.

THE COURT: All right. And if plaintiffs restrict

their evidence to that, I take it then you would agree that, for purposes of argument, you couldn't refer to anything other than the evidence in the record already developed and now the additional financial information?

MR. CHILDERS: Correct.

MR. LEWIS: But I would say that argument has already been made then, Your Honor. I mean, the argument about whatever is already in the record, well, that's what the jury has already found on. So that is why I'm concerned, is that they're going to argue the evidence that was already in the first phase of the trial and then reargue that evidence for different purposes here to talk about they haven't learned their lesson. And the jury is not getting the full story on that piece of it, even though it wasn't relevant for liability. That's what I'm concerned about.

My suggestion would be put in the evidence of financial worth, and then you just let the jury go back and deliberate based on the arguments and conduct that they've already heard without further argument by the lawyers, because he's already made those arguments in closing argument and throughout the trial.

THE COURT: Well, I don't know that I can prevent or prohibit the parties from making an additional closing statement about the punitive damages.

Yes, they've already heard the evidence and, based

upon that evidence, they have found the defendant liable for punitive damages. But by the terms of the instruction, the measurement of it has to be based upon the evidence they've already heard and apparently the financial standing evidence.

I don't think that I can stop the parties from arguing about that. And I don't think that that necessitates reopening the evidence for some more elaborate presentation of additional or new evidence by either side when it comes to the defendant's conduct and the basis for punitive damages.

And I will add this. I'm inclined to say that any argument here is going to be very short. I'm talking 10 minutes or 15 minutes, something like that, because I think this jury has already been here a long time and worked through and returned this verdict. I have no reason to question their ability to make this last determination fairly and promptly and without a lot of additional argument.

MR. LEWIS: May I just have, like, two minutes to confer --

THE COURT: Sure.

MR. LEWIS: -- based on what we've discussed?

THE COURT: Absolutely.

(Defense counsel conferring.)

THE COURT: Go ahead.

MR. LEWIS: So, Your Honor, we're prepared to go forward with just the video play and then brief arguments by

counsel.

Not the launch video.

MR. CHILDERS: I just told her to take out the launch video.

THE COURT: You're not offering the launch video?

MR. CHILDERS: No. It sounds like Your Honor just wants financial information.

THE COURT: I think that's correct. And --

MR. CHILDERS: That's fine.

THE COURT: So that's fine?

MR. CHILDERS: Yes.

THE COURT: All right. So are you ready to play this thing or --

MR. CHILDERS: Have you guys approved the play --

MR. LEWIS: With the launch video piece taken out?

MR. CHILDERS: Correct. It sounds like we're good to go, Your Honor.

How long is it? It's pretty short, Your Honor.

THE COURT: All right. I'm going to give I hope a very neutral, brief explanation to the jury that, as a result of their verdict, they found that there may be liability for so-called punitive damages, and that they need to determine what amount, if any, to award. And that you're going to have some brief evidence, some brief argument, I'm going to give them an instruction pertaining to that, and then they can go

back in and deliberate.

And in terms of the instruction, I don't know if you all have readily available the version of the punitive damage instruction that you submitted with the agreement as to what went in and the strikethrough about the damage part that we agreed to take out.

MR. CHILDERS: I'm certain we have it. I don't have it with me. Is it your intent that you would read it after the evidence, and then we would argue like you did with the other charge?

THE COURT: Yes.

MR. CHILDERS: I don't recall us having any issues.

Pattern charge, Your Honor?

THE COURT: Yes.

MR. CHILDERS: Okay.

THE COURT: I literally have my copy of the West Virginia pattern instruction, and for our purposes, I would start it at the section where it says there is no fixed formula to determine the amount, and then it lists 1, 2, 3, 4 and 5.

MR. MOSKOW: Thank you. I'm sorry.

(Counsel conferring.)

THE COURT: So what I think I'm proposing is I would just read the strikethrough that begins with there is no fixed formula that you all had in your joint proposal. We agreed

that this should not be read unless and until a punitive award was being actually considered by the jury. And that language looks to me like it tracks the pattern instruction and just puts in BI's name.

MR. MOSKOW: That's fine with the plaintiffs, Your Honor. Thank you.

MR. LEWIS: I mean, if it's the pattern, we have no objection.

THE COURT: All right. Let's bring the jury in.

(Jury present.)

THE COURT: All right. Ladies and Gentlemen, thank you for your patience. So, first, I want to explain to you what we are doing now.

In your verdict form, you found that the defendant BI is liable for fraud. You then determined that, as a result of that fraud, plaintiffs had proven that Betty Knight was proximately injured, and you awarded damages for economic damages of $50,000, non-economic damages of $200,000. Of course, you did not find in favor of the plaintiffs that the fraud caused the death of Betty Knight, and you did not make any award under wrongful death.

And then the very last question asked of you was whether the plaintiffs proved by clear and convincing evidence that BI acted with actual malice or with a conscious, reckless or outrageous indifference to the health, safety or welfare of

others. And, of course, you checked Yes to that.

As a result, plaintiffs are entitled to additional punitive damages, if any, to be determined by you. As a result, we're going to conduct what I believe to be relatively brief proceedings next where some limited evidence is going to be entered that you'll hear. Then the lawyers will then make brief closing statements only about the amount, if any, of punitive damages that you would award based on the evidence that you've heard, the determination that you've made and this additional evidence, and then ask for you to return a supplemental verdict as to that question only.

Are the parties satisfied with my explanation of this step?

MR. CHILDERS: Yes, Your Honor.

MR. LEWIS: Yes, Your Honor.

THE COURT: All right. Plaintiffs have indicated that you have a short deposition to be played?

MR. CHILDERS: Yes.

THE COURT: You want to introduce it?

MR. CHILDERS: This is a very brief deposition of Andreas Barner, who was the CEO of Boehringer Ingelheim during the time Betty Knight ingested Pradaxa.

ANDREAS BARNER, PLAINTIFFS' WITNESS,

October 2017 videotaped deposition played.)

MR. CHILDERS: That's the end of the play, Your Honor.

THE COURT: All right. That concludes the evidence from the plaintiffs.

Is defendant offering anything else at this point?

MR. LEWIS: No, Your Honor.

THE COURT: All right. I'm now going to instruct you as to the law that you're to apply, and then we're going to let the lawyers have a few minutes of argument about this.

Again, we're only focusing now on whether you as a jury agree to award an amount of punitive damages. It is entirely up to you folks to make that determination. Your verdict must be unanimous.

There is no fixed formula to determine the amount of punitive damages, but you cannot pull numbers out of the air. If you decide to award punitive damages, you should consider the following factors in determining the amount of punitive damages:

First, punitive damages should bear a reasonable relationship to the harm that is likely to occur from the defendant's conduct, as well as the harm that actually occurred. If the defendant's actions caused or likely caused in a similar situation only slight harm, the punitive damages should be relatively small. If the harm or potential harm was severe, the punitive damages should be greater.

Second, you may consider whether the defendant's conduct was reprehensible and, in doing so, you should take

into account how long the defendant continued in its actions; whether the defendant was aware that its actions were causing or likely to cause harm; whether the defendant attempted to conceal or cover up actions or harm caused by such actions; and, D, how often the defendant engaged in similar conduct in the past.

Third, you may consider whether the defendant profited from its wrongful conduct. And if you find that the defendant did profit from its conduct, you may remove the profit, and your award may be in excess of the profit so that the award discourages future bad acts by the defendant.

Fourth, as a matter of fundamental fairness, punitive damages must bear a reasonable relationship to the compensatory damages.

Last, in determining the amount of punitive damages, the financial position of the defendant is relevant.

With that, each side will get about 10 minutes to argue. The argument is restricted to the evidence just heard about the financial position of the defendant and to the record already before this jury in the case in chief.

MR. MOSKOW: Just a second, Your Honor.

THE COURT: Certainly.

MR. CHILDERS: Let me start by thanking you and continue by saying I'm sorry you're still here. I'm going to be brief.

What you just heard was the CEO of the company from the time Pradaxa was launched up until about 2015. What he explained to you was that this company, unlike basically any drug company in the world, is owned by one family, the Boehringer family, and it's been in their family since 1885. There are no public shares available. You can't own a piece of Boehringer Ingelheim. It's only owned by he said 30 to 40 people.

And what he also told you was that those 30 to 40 people split each year two billion Euros in profit. I don't know how Euros and dollars convert currently, but I know a Euro is worth more than a dollar. That's more than two billion dollars a year that these 30 to 40 people take home from Boehringer Ingelheim.

The reason I'm telling you that is because the purpose of punitive damages is to punish and deter. The amount of the award that you make has to be significant enough based on the defendant's financial position, how much money they have, to make them realize we can't do this any more. We need to do better. We need to do what is required by law.

And so based on that, I did some quick math, and I think my math is right. If you take two billion dollars a year, and you split that among those 30 to 40 people, every year, every year the profit that they take home is between 50 million and 66 million dollars each simply because they were

born in the Boehringer family.

It's been five years since Betty's bleed. Each of those people has taken home 250 million to 333 million dollars, each of them.

You also heard from Dr. Barner that the profits of the company increased by 200 million dollars a year just when they started selling Pradaxa. That's how big of an impact this drug made on their company.

The judge told you your award has to have a reasonable relationship to the harms that are likely to occur if this conduct continues in the future. What does that mean? Pradaxa is still on the market. Hundreds of thousands of people still take it. People still have severe bleeds and will have severe bleeds. People will die from those bleeds. That is the kind of injury that your award should serve to deter Boehringer from causing in the future.

And then the other thing that the judge told you is your award may bear a reasonable relationship to the harm that has already occurred, and you've already decided that. You decided the award to make for Betty's injuries.

I would encourage you to send a clear and decisive verdict on punitive damages back to this company. Let them know this can't happen in West Virginia. Make it so that they feel the pain that Betty Knight felt, that they feel the pain that they are inflicting currently on other people like Betty

Knight who are taking Pradaxa and don't have any idea of the damage it is doing to them.

Thank you.

THE COURT: All right. For the defense, Mr. Lewis.

MR. LEWIS: Thank you, Your Honor.

May it please the Court, members of the jury, counsel.

Ladies and Gentlemen, let me first start by saying how appreciative we are for your time and your service as jurors. You've put in a lot of time and effort, and we sit over at that table, and we peek over at you sometimes. And I can tell you from my perspective, all of you were paying attention throughout the entire trial, listening to the evidence, listening to the witnesses and taking this very, very seriously.

The men and women at Boehringer take this very seriously, too. And I want you to know that your message today has been heard. And the things that have been brought out at this trial about 2010, 2011, have been heard. And I wanted to just remind you of a couple things before you go back and deliberate this next phase.

We heard folks when they said you need to update your label to include new information, and you saw that in the trial Boehringer continued to update the physician label over time. In November of 2011 and even as late as 2013, April of 2013, we had new information that was becoming available. And

that's important, that's what we want folks to do, continue to take information and put it out there.

We know that Boehringer continued to study, with the rest of the scientists in the world, the issue of whether monitoring of blood plasma levels should take place and published an article that you saw in the trial that talked about whether or not that should be done and have continued to do that through today.

And you also saw that the United States Food and Drug Administration was looking at the adverse events that came in when Pradaxa first came onto the market and, through the drug safety communications, consistently reaffirmed that Pradaxa was helpful to many, many people who had a very, very high stroke risk. I want you to consider that evidence, but I also want you to know that we've heard you.

There are hundreds and thousands of folks out there who need medication to prevent them from having a stroke. And warfarin was a good option for many, many years, and physicians were looking for something that they could also consider. And we know that the label through updates and through information, those options are still available today. Pradaxa is available as an option with many others to help people get better, to protect people from getting a stroke.

And we know from the evidence that Pradaxa is also very good at preventing other types of bleeds. But there's no

question about it, there is a higher risk of gastrointestinal bleed. We are studying that issue.

So I want you to consider both what you've heard at the underlying trial, but also the impact that any award would have on the continued science and development and research for medications like Pradaxa to help people fight and protect from stroke risk. I want you to consider that.

But at the end of the day, the most important thing that I want you to understand is that you've been heard. Your voice has been heard. This is a message, and Boehringer is going to continue, as you've seen throughout the trial, to update the label when appropriate, when new information becomes available, and it's going to continue to do that, and your message is going to be heard already, already.

Thank you for your time and service as jurors.

THE COURT: All right. I have prepared an additional supplemental verdict form. It's very simple. It asks what amount, if any, do you award as punitive damages.

So, with that, you may retire to the jury room to begin your deliberations. We'll bring this jury verdict form to you in just a few minutes.

(Off the record at 6:11 p.m.)

(Back on the record at 6:46 p.m.)

THE COURT: All right. We're advised the jury has a verdict on their last question.

Let's bring them out.

THE COURT SECURITY OFFICER: Yes, Your Honor.

(Jury present.)

THE COURT: All right. Mr. Sayre, you're the foreperson. Has the jury reached a verdict on the last question?

JURY NO. 26: Yeah, we have.

THE COURT: All right. Would you pass it to my court security officer? He'll bring it to me.

All right. I'll read your verdict aloud.

The form reads: We, the jury in the above-captioned matter, unanimously answer the following questions:

I. Punitive damages.

1. What amount, if any, do you award for punitive damages? One million dollars.

Then it is signed by Mr. Sayre and dated today.

So the Court will order that this verdict also be recorded and made a part of the record.

Do the parties want to poll the jury as to the verdict?

MS. JONES: No, Your Honor. Thank you.

THE COURT: If not, Ladies and Gentlemen, that concludes your work.

On behalf of all of us, we want to thank you for your hard work over these last three weeks. We know this has been

a lot to -- a huge interruption in your lives. I hope that you walk away from this with a feeling of satisfaction, because you should. You've contributed a very valuable public service.

With that, you're excused. You're free to go.

I would ask everyone else to remain in the courtroom until the jury has departed.

(Jury excused at 6:49 p.m.)

(Off the record.)

THE COURT: All right. You may be seated.

I'm going to enter judgment on the jury's verdict. I direct the parties to file any post-trial motions in writing within the next 28 days.

I've been advised by my courtroom deputy that one or more of the parties have expressed a desire to talk to jurors. Our general rule is, first, it can only be done upon notice and proper motion to the Court.

Secondly, it's always been our practice in this district that we will not allow lawyers to talk to jurors until those jurors have finished their jury service. These folks are on the October through December panel and so, in theory, they could be called to try additional cases between now and the end of the calendar year. So it's unlikely that I would be willing to permit counsel to talk to them before then, if at all. Okay?

MS. JONES: Understood, Your Honor.

THE COURT: All right. Is there anything else that we need to address here today?

MS. JONES: Your Honor, I think on behalf of all of the parties, I just want to say thank you to yourself and to your staff, who have been tremendous and very kind to us. So thank you very much.

THE COURT: Well, I said it while ago, and I meant it sincerely. I haven't seen finer lawyers in my courtroom for anything. And regardless of the outcome, you should each be proud of the work that you've done in this case.

MR. MOSKOW: Thank you very much, Your Honor.

MR. CHILDERS: Thank you, Your Honor.

MR. LEWIS: Thank you, Your Honor.

MS. JONES: Thank you, Judge.

THE COURT: We stand adjourned.

THE COURT SECURITY OFFICER: All rise. This honorable court will be adjourned.

(Proceedings were adjourned at 6:51 p.m.)

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CERTIFICATION:

We, Kathy L. Swinhart, CSR, and Lisa A. Cook, RPR-RMR-CRR-FCRR, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter as reported on October 17, 2018.

October 19, 2018
DATE

/s/ Kathy L. Swinhart
KATHY L. SWINHART, CSR

/s/ Lisa A. Cook
LISA A. COOK, RPR-RMR-CRR-FCRR